EXHIBIT B

Rachel E. Fitzpatrick (*admitted pro hac vice*)
Molly Booker (*admitted pro hac vice*)
HAGENS BERMAN SOBOL SHAPIRO LLP
11 West Jefferson Street, Suite 1000
Phoenix, AZ 85003
Telephone: (602) 840-5900
Facsimile: (602) 840-3012
mollyb@hbsslaw.com
rachelf@hbsslaw.com

Christopher Pitoun (SBN 290235)
HAGENS BERMAN SOBOL SHAPIRO LLP
301 North Lake Avenue, Suite 920
Pasadena, CA 91101
Telephone: (213) 330-7150
Facsimile: (213) 330-7152
christopherp@hbsslaw.com

Attorneys for the Pfaff Plaintiffs

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE:

PROPECIA (FINASTERIDE) PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT APPLIES TO:

Kelly S. Pfaff, individually, on behalf of J.A.P. and C.P., minors, and as Trustee of the Pfaff Family Trust

Plaintiffs,

v.

Merck & Co., Inc. and Merck Sharp & Dohme Corp,

Defendants.

AGT

No. CV-20 80148-MISC.

DECLARATION OF RACHEL E. FITZPATRICK IN SUPPORT OF MOTION TO QUASH OR MODIFY NONPARTY SUBPOENA AND MEMORANDUM OF POINTS AND AUTHORITIES

Hearing date: TBD
Hearing Time: TBD

I, Rachel E. Fitzpatrick, state and declare:

1. I am an attorney in the law firm Hagens Berman Sobol Shapiro LLP ("Hagens Berman") and counsel of record for the Pfaff Plaintiffs in the above-captioned litigation. I have personal knowledge of the facts stated within this Declaration. I could and would testify competently to the facts contained in this Declaration.

2. Attached as Exhibit A, is a true and correct copy of the *Pfaff* Complaint.

3. Attached as Exhibit B, is a true and correct copy of the *In re Propecia (Finasteride) Product Liability Litigation* multidistrict litigation Document Requests served on Plaintiffs.

4. In response to broad document requests served in the MDL, and informal follow-up requests from Merck, Plaintiffs have produced hundreds of documents in their possession, custody, or control, including information relating to Trace3. See PFAFF0001-1977 (productions not attached). Plaintiffs also obtained and produced Mr. Pfaff's employment file received from Trace3 via their own record request. *Id.*

5. In November 2019, Merck sought and obtained more than a hundred documents directly from Trace3 via authorizations Plaintiffs provided. See PfaffJ-Trace3-00001 - PfaffJ-Trace3-00102 (production not attached).

6. Plaintiffs obtained and produced data from Mr. Pfaff's cell phone, which includes data relating to Mr. Pfaff's employment with Trace3. See PFAFF001585-1977 (production not attached).

7. On August 13, 2020, Merck served Plaintiffs with a notice of intent to serve and copy of the Trace3 Subpoena, in accordance with MDL Practice and Procedure Order No. 6.

8. Attached as Exhibit C, is a true and correct copy of Practice and Procedure Order No. 6 from the *In re Propecia (Finasteride) Product Liability Litigation* multidistrict litigation.

9. On August 19, 2020, counsel for the Parties met and conferred regarding the Trace3 Subpoena. In response to this conversation, Merck revised Request No. 8 to the Trace3 Subpoena, but made no other changes.

10. Attached as Exhibit D, is a true and correct copy of the revised Trace3 Subpoena.

11. This week, Merck served specific terms for Plaintiffs to use in searching for responsive ESI data in their possession, custody, or control.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on August 28, 2020, at Phoenix, Arizona.

HAGENS BERMAN SOBOL SHAPIRO LLP

By:_____
Rachel E. Fitzpatrick

CERTIFICATE OF SERVICE

I, the undersigned, certify and declare that on August 28, 2020, I served a true copy of DECLARATION OF RACHEL E. FITZPATRICK IN SUPPORT OF PLAINTIFFS' MOTION TO QUASH OR MODIFY NONPARTY SUBPOENA AND MEMORANDUM OF POINTS AND AUTHORITIES by personally delivering it to the person indicated below by electronic mail.

Mac Plosser (mac.plosser@butlersnow.com)
Charles F. Morrow (chip.morrow@butlersnow.com)
Butler Snow LLLP
Crescent Center
6075 Poplar Avenue, Ste. 500
Memphis, TN 38119
Attorneys for Defendants Merck & Co., Inc.

Rachel Fitzpatrick

EXHIBIT A

ELAINE T. BYSZEWSKI (SBN 222304)
CHRISTOPHER R. PITOUN (SBN 290235)
HAGENS BERMAN SOBOL SHAPIRO LLP
301 North Lake Avenue, Suite 203
Pasadena, California 91101
Telephone: (213) 330-7150
Facsimile: (213) 330-7152
Email: elaine@hbsslaw.com
Email: christopherp@hbsslaw.com

ROBERT B. CAREY (*pro hac vice* pending)
RACHEL E. FREEMAN (*pro hac vice* pending)
HAGENS BERMAN SOBOL SHAPIRO LLP
11 West Jefferson Street, Suite 1000
Phoenix, Arizona 85003
Telephone: (602) 840-5900
Facsimile: (602) 840-3012
Email: rob@hbsslaw.com
Email: rachelf@hbsslaw.com

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

KELLY S. PFAFF, individually, on behalf of J.A.P. and C. P., minors, and as Trustee of the PFAFF FAMILY TRUST,

Plaintiffs,

v.

MERCK & CO., INC. and MERCK SHARP & DOHME, CORP.,

Defendants.

No. '15CV509 DMS BLM

COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

Plaintiff Kelly Pfaff, as trustee of the Pfaff Family Trust and individually and on behalf of her minor children, Plaintiffs J.A.P. and C. P., through their undersigned counsel, based on their individual experiences, the investigation of Counsel, and on information and belief, respectfully submits the following Complaint for damages arising from the injury to and wrongful death of her husband and the father of her children, John D. Pfaff.

I. INTRODUCTION

1. This suit arises out of the failure of Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. (together, "Merck" or "Defendant Merck") to warn of dangerous side effects in its prescription hair loss drug, Propecia. Propecia has known depression and suicide ideation side effects. But from the drug's inception in 1997 through late 2010, Defendant Merck never included these side effects, or the risk of developing them, on the Propecia label or literature distributed with the drug, even though these were reported side effects known or knowable to Defendant Merck. And to this day, Merck has never disclosed or explained the risks related to suicide ideation or suicidality.

2. John D. Pfaff, the husband and father of Plaintiffs Kelly, J.A.P., and C. P., was prescribed Propecia by his dermatologist in May 2008. Over the next two years of ingesting the drug as prescribed, John spiraled into a deep depression that lingered even after he stopped taking the drug in 2012. The Propecia-induced depression was followed by suicide ideation, and eventually, John took his own life. Because of Defendant Merck's strict negligence, negligence, and breach of express and implied warranties in failing to warn of these dangerous side effects, they are liable for the injury to and wrongful death of John D. Pfaff.

3. This case seeks wrongful death and survival action damages on behalf of Plaintiffs Kelly Pfaff, J.A.P., C. P., and the Pfaff Family Trust stemming from Defendant Merck's failure to warn of potential depression and suicide ideation side effects in prescription hair loss drug, Propecia. It does not seek damages stemming from Defendant Merck's failure to warn of the sexual dysfunction side effects caused by Propecia.

II. PARTIES

4. Plaintiff Kelly Pfaff, the surviving spouse of decedent John D. Pfaff, was a resident of Encinitas, California, in San Diego County, at all relevant times to this lawsuit. She resides in Park City, Utah with her two children. Kelly is also the sole, currently acting Trustee of the Pfaff Family Trust, of which the beneficiaries are Kelly Pfaff, J.A.P., and C. P.

5. Plaintiff J.A.P., the minor son of decedent John D. Pfaff and Kelly Pfaff, was a resident of Encinitas, California, in San Diego County, at all relevant times to this lawsuit. He resides in Park City, Utah with his mother and sister.

6. Plaintiff C.P., the minor daughter of decedent John D. Pfaff and Kelly Pfaff, was a resident of Encinitas, California, in San Diego County, at all relevant times to this lawsuit. She resides in Park City, Utah with her mother and brother.

7. On information and belief, Defendant Merck & Co., Inc. ("Merck & Co.") is a publicly-traded, global pharmaceutical corporation incorporated in the State of New Jersey and headquartered at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033, in Union County.

8. On information and belief, Defendant Merck Sharp & Dohme, Corp. ("Merck Sharp") is a wholly owned subsidiary of Defendant Merck & Co. On information and belief, Merck Sharp is incorporated in the State of New Jersey and headquartered at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033, in Union County.

9. Merck is a global health care company, which claims to "deliver innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products, which it markets directly and through its joint ventures."[1] Comprised of three operating segments, "[t]he Pharmaceutical segment includes human health pharmaceutical and vaccine products marketed either directly by the Company or through joint ventures."[2] Merck's pharmaceutical products include therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders.[3] Merck sells these products to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions.[4]

10. Merck's U.S. sales alone topped more than $17.1 billion in 2014. Propecia sales made up $264 million of Merck's total U.S. sales in 2014.

---

[1] MERCK.COM, Annual Form 10-K dated Feb. 27, 2015 *available at* http://www.merck.-com/investors/financial-reports/sec-filings.html (last visited Mar. 3, 2015).

[2] *Id.*

[3] *Id.*

[4] *Id.*

III. JURISDICTION AND VENUE

11. This Court has diversity jurisdiction over this action under 28 U.S.C. § 1332(a) because the amount in controversy exceeds $75,000, and Plaintiffs are citizens of a different state than Defendant Merck.

12. This Court has personal jurisdiction over Plaintiffs because Plaintiff Kelly Pfaff submits to the Court's jurisdiction. This Court has personal jurisdiction over Defendant Merck because it conducts substantial business in California.

13. Defendant Merck is headquartered in Kenilworth, New Jersey, but, on information and belief, it conducts or conducted substantial business in this District by marketing and selling its prescription drug products, including Propecia.

14. Venue is proper in this District under 28 U.S.C. § 1391(2) because "a substantial part of the events or omissions giving rise to the claim occurred in this District." Decedent John D. Pfaff, the subject of this wrongful death suit, was prescribed, purchased, and ingested Defendant Merck's prescription drug in this District. He also committed suicide in this District. Finally, venue is proper under 28 U.S.C. § 1391(3) because Defendant Merck, as a corporation, is "deemed to reside in any judicial district in which they are subject to personal jurisdiction," and because of Defendant Merck's numerous contacts with this District described in the preceding paragraph.

IV. FACTUAL ALLEGATIONS

A. Merck Develops, Manufactures, Markets, and Sells Propecia, But Fails To Warn About Its Dangerous Mental Health Side Effects.

15. In or around December 1997, after receiving Federal Drug Administration ("FDA") approval, Merck began manufacturing, marketing, and selling the prescription drug Propecia throughout the United States.

16. Propecia is a one (1) milligram tablet of finasteride for prescription use in males only to treat male pattern hair loss.

17. Finasteride belongs to a class of prescription medicines called 5α-reductase inhibitors ("5-ARIs") used primarily to treat benign prostatic hyperplasia and androgenic alopecia. Finasteride is a Type II 5-ARI that prevents the conversion of testosterone into dihydrotestosterone ("DHT").

The primary cause of androgenic alopecia, or male pattern balding, is the conversion of testosterone to dihydrotestosterone ("DHT"). By inhibiting 5α-reductase, finasteride prevents conversion of testosterone to DHT in the hair follicles. Because DHT affects an insulin-like growth factor in the hair follicles important in the development of healthy hair shafts, by blocking DHT production, finasteride reduces hair loss.

18. At the time of Propecia's approval and release, Merck did not include the side effects of depression, suicide ideation, or similar cognitive issues, or the risks of developing these, associated with the drug in its labeling.

19. In fact, Merck promoted the use of Propecia for treatment of male pattern hair loss as safe for its intended use.

20. Suicide ideation is defined as "thinking about, considering, or planning for suicide" by the Centers for Disease Control and Prevention.[5]

21. Depression, by contrast, is characterized by "depressed or sad mood, diminished interest in activities which used to be pleasurable, weight gain or loss, psychomotor agitation or retardation, fatigue, inappropriate guilt, difficulties concentrating, as well as recurrent thoughts of death."[6] The "diagnostic criteria established by the American Psychiatric Association dictate that five or more of the above symptoms must be present for a continuous period of at least two weeks."[7] While depression can lead to suicide ideation, the two are distinct, as suicide ideation presents a separate side effect with a heightened risk to the afflicted person.

22. For other drugs on the market with links to suicide ideation, the FDA has proposed warning labels clearly outlining the side effects, and risk of developing them, to the drug's users. For example, in antidepressants, the FDA proposed updates in the box warning at the beginning of the package insert, in the "WARNINGS-Clinical Worsening and Suicide Risk," and in the

[5] Injury Prevention & Control: Division of Violence Prevention, CDC.GOV, http://www.cdc.-gov/violenceprevention/suicide/definitions.html (last visited Mar. 4, 2015).

[6] Mental Illness, Centers for Disease Control and Prevention, CDC.GOV, http://www.cdc.gov/-mentalhealth/basics/mental-illness/depression.htm (last visited Mar. 4, 2015).

[7] *Id.*

"PRECAUTIONS-Information for Patients" sections of the products' labels. The proposed language conveyed the dangers in a clear, comprehensive manner:

- "**Suicidality and Antidepressant Drugs - Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of [Insert established name] or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber.**" (Emphasis in original.)[8]

- "Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs."[9]

- "There has been a longstanding concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled trials of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older."[10]

- "**All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.**"[11] (Emphasis in original.)

---

[8] Antidepressant Use in Children, Adolescents, and Adults, FDA.GOV, http://www.fda.gov/-downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM173233.pdf (Last visited Mar. 5, 2015).

[9] *Id.*

[10] *Id.*

[11] *Id.*

- **"Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers. Such monitoring should include daily observation by families and caregivers."**[12] (Emphasis in original.)

23. Similarly, in 2005, after reports of suicide ideation in the prescription drug Accutane—a cosmetic drug, like Propecia—the manufacturer updated the label to include these side effects even though the mechanism of action was not yet known:

> **Psychiatric Disorders**
>
> **Accutane (isotretinoin) may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors. No mechanism of action has been established for these events (see ADVERSE REACTIONS: Psychiatric). Prescribers should read the brochure, *Recognizing Psychiatric Disorders in Adolescents and Young Adults: A Guide for Prescribers of Isotretinoin*. Prescribers should be alert to the warning signs of psychiatric disorders to guide patients to receive the help they need. Therefore, prior to initiation of Accutane (isotretinoin) therapy, patients and family members should be asked about any history of psychiatric disorder, and at each visit during therapy patients should be assessed for symptoms of depression, mood disturbance, psychosis, or aggression to determine if further evaluation may be necessary. Signs and symptoms of depression, as described in the brochure ("Recognizing Psychiatric Disorders in Adolescents and Young Adults"), include sad mood, hopelessness, feelings of guilt, worthlessness or helplessness, loss of pleasure or interest in activities, fatigue, difficulty concentrating, change in sleep pattern, change in weight or appetite, suicidal thoughts or attempts, restlessness, irritability, acting on dangerous impulses, and persistent physical symptoms unresponsive to treatment. Patients should stop Accutane (isotretinoin) and the patient or a family member should promptly contact their prescriber if the patient develops depression, mood disturbance, psychosis, or aggression, without waiting until the next visit. Discontinuation of Accutane (isotretinoin) therapy may be insufficient; further evaluation may be necessary. While such monitoring may be helpful, it may not detect all patients at risk. Patients may report mental health problems or family history of psychiatric disorders. These reports should be discussed with the patient and/or the patient's family. A referral to a mental health professional may be necessary. The physician should consider whether Accutane (isotretinoin) therapy is appropriate in this setting; for some patients the risks may outweigh the benefits of Accutane (isotretinoin) therapy.**

(Emphasis in original.)

[12] *Id.*

24. In October 2006, BioMed Central, a scientific publisher specializing in open access journal publication, published a study indicating that Propecia may cause depression.[13] The study was prompted by previous animal studies, and some human case reports, suggesting finasteride could alter 5-ARI activity in some regions of the brain, leading to behavioral and mood changes.[14] Researchers enrolled 128 men with androgenic alopecia who were prescribed 1 mg/day of finasteride.[15] To gather information on depressed mood and anxiety, participants completed Beck Depression Inventory ("BDI") and Hospital Anxiety and Depression Scale ("HADS") questionnaires before beginning the finasteride treatment, and again two months after it.[16] The preliminary study concluded finasteride might induce depressive symptoms, and therefore these behavioral side effects should be considered specially when prescribed for patients more susceptible to them.[17] The study also recommended further studies "to elucidate behavioral effects of finasteride in higher doses and in high risk groups..."[18]

25. On information and belief, Merck failed to warn U.S. clinicians and patients of depression and suicide ideation side effects associated with Propecia in or around May 2008.

26. Merck's failure to warn of these cognitive side effects contradicted its response to new information about the sexual side effects associated with the drug. When Merck first released Propecia in 1997, some sexual side effects, such as decreased libido, erectile dysfunction, and ejaculate disorder, were reported in the initial Propecia labeling, but Merck represented these were only temporary. After the Swedish Medical Products Agency commenced an investigation into Merck's representations and concluded Propecia can cause permanent sexual dysfunction, in 2008, Merck changed its Swedish label to warn of these effects, and on information and belief, later changed Propecia labels in the United Kingdom and Italy. Finally, around June 2011 and again in

---

[13] BMC Pharmacology & Toxicology, BIOMEDCENTRAL.COM, http://www.biomedcentral-.com/-1472-6904/6/7 (last visited Mar. 3, 2015).

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

April 2012, Merck made significant and well-publicized updates to the Propecia label, admitting many of the reported sexual side effects persisted after discontinuation of the drug.

27. But when it came to Propecia's depression and suicide ideation side effects, Merck largely ignored clinical findings it knew or should have known about. It was not until December 2010, at earliest, when Merck updated Propecia's professional label to include "depression" as a side effect in the Adverse Reactions Postmarketing Experience section of the labeling and the Patient Package Insert.[19]

28. The December 2010 label omits suicide ideation altogether.

29. Even after Merck's significant updates in April 2012 in light of the sexual dysfunction findings, the new Propecia label made scant mention of the depression in the Adverse Reactions Postmarketing Experience section of the labeling and the Patient Package Insert, and did not mention suicide ideation.[20]

30. In August 2012, Dr. Michael Irwig of George Washington University published a retrospective study highlighting a link between Propecia and depression and suicide ideation, and concluding men who took Propecia for hair loss and experienced its sexual side effects also had high rates of depressive symptoms, even after stopping the drug.[21]

31. Among the group of former Propecia users who developed persistent sexual dysfunction, 75 percent reported symptoms of depression compared with 10 percent of controls who never took the drug.[22] The symptoms were moderate-to-severe in 64 percent of the former Propecia users and in none of the controls.[23]

[19] Ex. A, Propecia Label dated December 2010.

[20] Ex. B, Propecia Label dated April 2012.

[21] Michael S. Irwig, M.D., *Depressive Symptoms and Suicidal Thoughts Among Former Users of Finasteride With Persistent Sexual Side Effects*, J. CLINICAL SOC'Y, Aug. 7, 2012, *available at* http://www.psychiatrist.com/_layouts/PPP.Psych.Controls/ArticleViewer.ashx?ArticleURL=/JCP/article/Pages/2012/v73n09/v73n0911.aspx (last visited Mar. 3, 2015).

[22] *Id.*

[23] *Id.*

32. Significantly, 39 percent of the former Propecia users reported having thoughts of suicide, and 5 percent agreed with the statement, "I would like to kill myself."[24] Only one member of the control group, which was less than half the size of the former Propecia users' sample, reported suicidal thoughts.[25]

33. Dr. Irwig's study was prompted by earlier studies and reports suggesting the link between Propecia and depression and suicide ideation. To reach his results, Dr. Irwig administered standardized interviews to 61 men who were former users of finasteride with persistent sexual side effects for over three months, gathering demographic information, medical and psychiatric histories, and information on medication use, sexual function, and alcohol consumption.[26] All of the former finasteride users were otherwise healthy men with no baseline sexual dysfunction, medical conditions, psychiatric conditions or use of oral prescription medications.[27] Dr. Irwig also conducted interviews with a control group of 29 men who had male pattern hair loss but who had never used finasteride and denied any history of psychiatric conditions or use of psychiatric medications.[28] Both groups self-administered the Beck Depression Inventory II (BDI-II), a widely used, validated instrument that measures the severity of depression in adults.[29]

34. Based on his findings, Dr. Irwig recommended clinicians and potential users of Propecia be warned of the potential risk of depressive symptoms and suicidal thoughts. He also suggested further research on the topic was warranted.[30]

35. On information and belief, Merck has yet to update its Propecia label to adequately address the dangerous depression side effect, nor warn of suicide ideation as a side effect.

---

[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] *Id.*

B. The Pfaff Family

36. John and Kelly met on April 12, 1996, in San Diego, California. The two were married June 8, 2002. They purchased their first home, a fixer-upper, in Encinitas, California. It was here they welcomed their first child on July 26, 2005.

37. John was finding success at his job at the EMC Corporation, a computer data storage company, which afforded the couple the ability to purchase a coastal home.

38. An avid team sport player in high school and college, John maintained his active lifestyle after college. He loved to surf and snow ski whenever he had the chance, and he worked out with a trainer once or twice per week. He often helped Kelly around the home, and enjoyed coaching his child's soccer team.

39. In or around May 2005, John took a position with a smaller, innovative IT consulting firm, Trace3. The role gave John the opportunity to build something from scratch, something he relished. John was a leader and communicator. While at Trace3, John helped expand the business into San Diego, from a single-run territory to a full office of people. He was later promoted to President of Trace3 in January 2010.

40. When Kelly became pregnant with their second child in 2007, the couple decided to buy a nearby property and contemplated a remodel of their original Encinitas cottage or building a brand new home. The move made sense given a second child was coming. Their daughter was born on August 13, 2008.

C. John Starts Taking Propecia And His Mental Health Begins To Steadily Decline

41. On May 6, 2008, John visited Dr. David E. Thomas at the Dermatologist Medical Group of North County in Encinitas, California. After evaluation, Dr. Thomas prescribed Propecia for John's hair loss, and John filled his first prescription on May 7, 2008. John was diligent about taking his Propecia as prescribed—1 milligram pill daily.

42. Defendant Merck and the Propecia labeling did not warn Dr. Thomas or John that depression or suicide ideation were potential side effects associated with the drug.

43. In 2009, John, for the first time, displayed an odd and troublesome attitude. He and Kelly would begin fighting over something small and insignificant, and then things escalated from there,

which was atypical because they rarely argued before this issue emerged. These fights left Kelly confused, hurt, and angry because she did not understand the change in her husband. Usually calm and confident, John expressed anxiety, extreme worry, and negative feelings. His sex drive also dwindled, which Kelly initially attributed to having young children.

44. From there, John's temperament drastically changed and his suffering intensified. By 2011, things unraveled and Kelly no longer recognized the man she married. Over the next two years John would suffer from a lack of sex drive, anxiety, depression, short temper, uncharacteristic weight gain despite being active and healthy, alarmingly repetitious behavior, impaired decision-making, low confidence, extreme insomnia, anger, suicide ideation, and social withdrawal.

45. In or around September 2011, John suffered a panic attack. The panic attack concerned John because it was the first he had ever experienced and it happened suddenly. He was also concerned because he did not understand what triggered it. It was around the same time of this first panic attack that John's decreased libido grew progressively worse.

46. A few months later, around December 2011, John suffered a second panic attack. John was excessively sweating, shaking, and making suicidal comments during this panic attack.

47. John filled his Propecia prescription for the last time on February 22, 2012. After he and Kelly discussed their diminished sex life, they decided he should stop taking the prescription in case it might be contributing to his decreased libido.

48. Around May 2012, John was increasingly angry and aggressive, yelling at family members, and acting outside his normal behavior. John also suffered from severe insomnia. By this time, his libido problems had escalated. John uncharacteristically gained weight despite his active and healthy lifestyle.

49. Still, John's odd behavior only worsened. He was fatigued and often napped during the day. He complained of unexplained muscle twitching and shaking in his legs and abnormal body temperatures. John also experienced cognitive dysfunction. His thought processing slowed, he often repeated himself over and over again, and his problem-solving skills were impaired, preventing him from resolving simple matters. He was "checked-out" emotionally, and Kelly describes John as "in a fog," highly depressed, and numb.

50. Before taking Propecia, John never suffered from depression, suicide ideation, anxiety, or other cognitive issues. He never experienced insomnia or a diminished libido either.

51. John's symptoms worsened and persisted, and on January 7, 2013, he suddenly resigned as President of Trace3. After he quit, Kelly remembers John acting confused and without any confidence, direction, or hope.

52. Still perplexed and shocked by his own abrupt resignation, John sent a bizarre and uncharacteristic email to Trace3 executives on January 10, 2013, confessing he had erred in resigning, begging for his job back, and asking for forgiveness. Trace3 declined to re-hire John.

53. During January and February 2013, John could not sleep more than a few hours each night for approximately 45 days. This was John's most prolonged and disturbing bout of insomnia.

D. John Ends His Life

54. On the morning of March 5, 2013, John left the Pfaff home without notice. When he left, Kelly was driving Aidan to school and the family's housekeeper had just arrived at the home. John's absence was noted by Kelly when she returned and she discovered John failed to take their daughter to school as planned.

55. John walked approximately one block from the house to the nearby Amtrak railroad tracks. He stepped in front of an oncoming train and was immediately killed on impact. John was 40 years old.

E. The Pfaff Family Without John

56. John's untimely death left Kelly, the children, and their extended family devastated and traumatized. Kelly was suddenly without her husband, and her children without their father. John had been the family patriarch and sole bread-winner. Compounding this loss was that Kelly could not understand or explain what had so drastically changed her husband, leading him to take his own life.

57. Immediately after learning of John's death, Kelly fell into a deep state of shock and panic. Her entire body visibly shook for several days after he died. Aside from her grief, she was fearful for the future of her family. Kelly was a stay-at-home mom to the kids, and without John, she had many expenses to cover but no income and no resume or career to fall back on.

58. Around May 2013, the Pfaff family learned of the depression and suicide ideation side effects associated with Propecia use.

59. Providing for her children weighs heavily on Kelly, and she struggles to support them. As leftover income and assistance depletes, Kelly must find a job that will permit her to monetarily support her growing children while also caring for them physically and emotionally.

60. Kelly and the children continue to see therapists to deal with the grief of this loss. But their lives are forever changed by John's absence. While playing games, their daughter, now 6-years-old, often pretends John is playing with her. Their son, now 9-years-old, has struggled with anxiety, anger, and worry. He feels pressure to protect Kelly and his sister as the only male in the house. Kelly worries about the impact the loss of such an important relationship will have on the kids' lives. Kelly is crippled by loneliness and sadness from losing the love of her life.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

(Strict Product Liability – Failure to Warn)

61. Plaintiffs incorporate by reference all allegations in the foregoing paragraphs.

62. Defendant Merck developed, manufactured, marketed, and sold Propecia during all relevant times alleged herein.

63. As a prescription drug manufacturer, Defendant Merck had a duty to warn of known or reasonably scientifically knowable side effects posed by Propecia, and the risk thereof.

64. As a drug manufacturer, Defendant Merck had a duty to maintain the content of its drug labels, including Propecia. Defendant Merck was required to both craft an adequate label for Propecia, and ensure that its warnings remain adequate if Propecia is on the market.

65. Propecia had potential side effects of depression and suicide ideation that were known or knowable to Defendant Merck in light of the scientific and medical knowledge that was generally accepted in the scientific community at the relevant times of Propecia's manufacture, marketing, distribution, and sale.

66. The side effects of depression and suicide ideation, and the risks thereof, present substantial dangers when Propecia is used or misused in an intended or reasonably foreseeable way.

67. Ordinary consumers would not have recognized the potential side effects of depression and suicide ideation posed by Propecia, nor the risk thereof.

68. John D. Pfaff used Propecia in a foreseeable manner.

69. Defendant Merck failed to warn John D. Pfaff, individually and/or through his prescribing physicians, about Propecia's potential side effects of depression and suicide ideation, and the risk of developing such side effects, and Defendant Merck continues to conceal that Propecia has the potential side effect of suicide ideation, and the risks thereof.

70. John D. Pfaff was harmed, and ultimately killed, by Propecia as described.

71. Defendant Merck's lack of sufficient warning was a substantial factor in causing John's injuries and death.

SECOND CAUSE OF ACTION

(Negligence – Failure to Warn)

72. Plaintiffs incorporate by reference all allegations in the foregoing paragraphs.

73. Defendant Merck developed, manufactured, marketed, and sold Propecia during all relevant times alleged herein.

74. As a prescription drug manufacturer, Defendant Merck had a continuing duty to exercise due care in warning of Propecia's potential side effects of depression and suicide ideation, and the risk thereof.

75. Defendant Merck knew or reasonably should have known that Propecia was dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner.

76. Defendant Merck knew or reasonably should have known that John D. Pfaff, individually and/or through his prescribing physicians, would not realize the dangers posed by Propecia of potential depression or suicide ideation, or both.

77. Defendant Merck failed to warn John D. Pfaff, individually and/or through his prescribing physicians, of the dangers of potential depression and/or suicide ideation posed by Propecia.

78. A reasonable prescription drug manufacturer, under the same or similar circumstances, would have warned of the dangers of potential depression or suicide ideation, or both, posed by Propecia.

79. Defendant Merck's failure to warn was a substantial factor in causing John's psychological condition.

80. Propecia harmed, and ultimately caused the death of, John D. Pfaff, as described.

THIRD CAUSE OF ACTION

(Breach of Implied Warranties – Failure to Warn)

81. Plaintiffs incorporate by reference all allegations in the foregoing paragraphs.

82. At all relevant times, Defendant Merck was in the business of manufacturing and selling Propecia and other pharmaceuticals to physicians and their patients.

83. At all relevant times, Defendant Merck knew of the intended use of Propecia and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

84. John D. Pfaff, individually and/or by and through his prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendant Merck.

85. John D. Pfaff purchased Propecia manufactured by Defendant Merck.

86. Defendant Merck breached these representations and warranties, as they were false, misleading, and inaccurate in that Propecia was not safe for its intended use and was not of merchantable quality because Defendant Merck failed to warn that Propecia could (1) lead to depression or (2) induce suicide ideation and increase the risk thereof, or both.

87. As a direct and proximate result of Defendant Merck's breach of implied warranties, John D. Pfaff was harmed, and ultimately killed, as described herein.

88. Propecia's failure to be as warranted by Defendant Merck was a substantial factor in causing John's injuries and death.

FOURTH CAUSE OF ACTION

(Breach of Express Warranties – Failure to Warn)

89. Plaintiffs incorporate by reference all allegations in the foregoing paragraphs.

90. Defendant Merck expressly represented to John D. Pfaff, individually and/or by and through his prescribing physicians, that Propecia was safe and fit for its intended purposes to treat male pattern hair loss.

91. John D. Pfaff, individually and/or by and through his prescribing physicians, reasonably relied upon Defendant Merck's express warranties and guarantees that Propecia was safe, merchantable, and reasonably fit for its intended purpose in choosing to treat male pattern hair loss.

92. Propecia did not conform to these express representations because its labeling failed to adequately warn of the potential side effects of depression and suicide ideation, and the risks thereof.

93. Defendant Merck breached its express warranties because Propecia was not as Merck had represented.

94. As a direct and proximate result of Defendant Merck's breach of express warranties, John D. Pfaff was harmed, and ultimately killed, as described herein.

95. Propecia's failure to be as warranted by Defendant Merck was a substantial factor in causing John's injuries and death.

FIFTH CAUSE OF ACTION

(Wrongful Death – On behalf of Kelly Pfaff, J.A. Pfaff, and C. Pfaff)

96. Plaintiffs incorporate by reference all allegations in the foregoing paragraphs.

97. The death of John D. Pfaff was directly and proximately caused by the strict negligence, negligence, and breach of warranties by Defendant Merck, as alleged herein.

98. Plaintiff Kelly Pfaff, the surviving spouse of John D. Pfaff, suffered pecuniary damages, loss of John's services, guidance, and advice, and loss of John's love, society, comfort, care, affection, solace, moral support, protection, companionship, and consortium arising from the death of her husband.

99. Plaintiffs J.A.P. AND C.P., the surviving children of John D. Pfaff, suffered pecuniary damages, loss of John's services, guidance, training, and advice, and loss of John's love, society, comfort, care, affection, solace, moral support, protection, and companionship arising from the death of their father.

SIXTH CAUSE OF ACTION

(Survival Action – Kelly Pfaff, as Trustee and Surviving Spouse, on behalf of John D. Pfaff's Estate)

100. Plaintiffs incorporate by reference all allegations in the foregoing paragraphs.

101. Defendant Merck was strictly negligent, negligent, and breached warranties in failing to warn or adequately warn of Propecia's potential side effects, and the risks thereof, as described herein.

102. Defendant Merck's acts and conduct directly and proximately caused injury to John D. Pfaff, as described herein.

103. Because of Defendant Merck's actions described herein, John D. Pfaff suffered pecuniary and punitive damages.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, pray for judgment against Defendants as follows:

A. For all compensatory damages caused by Defendants' conduct;

B. For all incidental and consequential damages caused by Defendants' conduct;

C. For exemplary or punitive damages;

D. For the maximum interest provided by law on such monetary relief, including but not limited to, Cal. Civ. Code § 3291;

E. Attorney's fees;

F. Costs of suit; and

G. For such other and further relief as the Court deems proper and just.

VII. JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all issues triable of right by jury.

DATED: March 5, 2015

HAGENS BERMAN SOBOL SHAPIRO LLP

By: /s/ Christopher R. Pitoun

Christopher R. Pitoun (SBN 290235)
Elaine T. Byszewski (SBN 222304)
HAGENS BERMAN SOBOL SHAPIRO LLP
301 North Lake Avenue
Pasadena, California 91101
Telephone: 213-330-7150
Facsimile: 213-330-7152
Email: christopherp@hbsslaw.com
Email: elaine@hbsslaw.com

Robert B. Carey (*pro hac vice* pending)
Rachel E. Freeman (*pro hac vice* pending)
HAGENS BERMAN SOBOL SHAPIRO LLP
11 West Jefferson Street, Suite 1000
Phoenix, Arizona 85003
Telephone: 602-840-5900
Facsimile: 602-840-3012
Email: rob@hbsslaw.com
Email: rachelf@hbsslaw.com

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

15CV509 DMS BLM

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

KELLY S. PFAFF, individually, on behalf of J.A.P. and C.P., minors, and as Trustee of the PFAFF FAMILY TRUST,

(b) County of Residence of First Listed Plaintiff Summit
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Christopher R. Pitoun HAGENS BERMAN SOBOL SHAPIRO LLP
301 North Lake Avenue, Suite 203, Pasadena, CA 98101
(213) 330-7150

DEFENDANTS

MERCK & CO., INC. and MERCK SHARPE & DOHME CORP.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332(a)

Brief description of cause:
Wrongful death and survival action for products liability involving prescription drug

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
03/05/2015

SIGNATURE OF ATTORNEY OF RECORD
/s/ Christopher R. Pitoun

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

ATTACHMENT TO THE CIVIL COVER SHEET – SECTION I (C)

Attorneys for the Plaintiffs

Elaine T. Byszewski (#22304)
Christopher R. Pitoun (#290235)
HAGENS BERMAN SOBOL SHAPIRO LLP
301 North Lake Avenue
Pasadena, California 91101
Telephone: 213-330-7150

Robert B. Carey (*Pro Hac Vice pending*)
Rachel E. Freeman (*Pro Hac Vice pending*)
HAGENS BERMAN SOBOL SHAPIRO LLP
11 West Jefferson Street, Suite 1000
Phoenix, Arizona 85003
Telephone: 602-840-5900

TABLE OF EXHIBITS

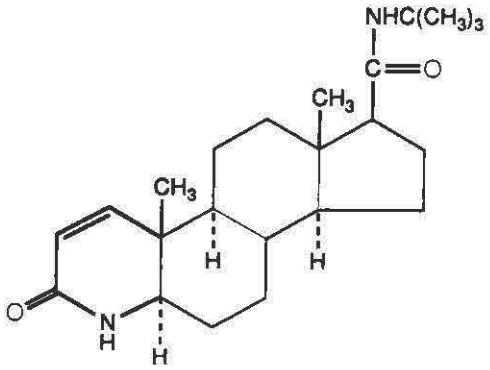
EXHIBIT A

PROPECIA®
(finasteride)
Tablets, 1 mg

DESCRIPTION

PROPECIA® (finasteride), a synthetic 4-azasteroid compound, is a specific inhibitor of steroid Type II 5α-reductase, an intracellular enzyme that converts the androgen testosterone into 5α-dihydrotestosterone (DHT).

Finasteride is 4-azaandrost-1-ene-17-carboxamide,*N*-(1,1-dimethylethyl)-3-oxo-,(5α,17β)-. The empirical formula of finasteride is $C_{23}H_{36}N_2O_2$ and its molecular weight is 372.55. Its structural formula is:



Finasteride is a white crystalline powder with a melting point near 250°C. It is freely soluble in chloroform and in lower alcohol solvents but is practically insoluble in water.

PROPECIA tablets for oral administration are film-coated tablets that contain 1 mg of finasteride and the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, hydroxypropyl methylcellulose, hydroxypropyl cellulose LF, titanium dioxide, magnesium stearate, talc, docusate sodium, yellow ferric oxide, and red ferric oxide.

CLINICAL PHARMACOLOGY

Finasteride is a competitive and specific inhibitor of Type II 5α-reductase, an intracellular enzyme that converts the androgen testosterone into DHT. Two distinct isozymes are found in mice, rats, monkeys, and humans: Type I and II. Each of these isozymes is differentially expressed in tissues and developmental stages. In humans, Type I 5α-reductase is predominant in the sebaceous glands of most regions of skin, including scalp, and liver. Type I 5α-reductase is responsible for approximately one-third of circulating DHT. The Type II 5α-reductase isozyme is primarily found in prostate, seminal vesicles, epididymides, and hair follicles as well as liver, and is responsible for two-thirds of circulating DHT.

In humans, the mechanism of action of finasteride is based on its preferential inhibition of the Type II isozyme. Using native tissues (scalp and prostate), *in vitro* binding studies examining the potential of finasteride to inhibit either isozyme revealed a 100-fold selectivity for the human Type II 5α-reductase over Type I isozyme (IC_{50}=500 and 4.2 nM for Type I and II, respectively). For both isozymes, the inhibition by finasteride is accompanied by reduction of the inhibitor to dihydrofinasteride and adduct formation with NADP+. The turnover for the enzyme complex is slow ($t_{1/2}$ approximately 30 days for the Type II enzyme complex and 14 days for the Type I complex).

Finasteride has no affinity for the androgen receptor and has no androgenic, antiandrogenic, estrogenic, antiestrogenic, or progestational effects. Inhibition of Type II 5α-reductase blocks the peripheral conversion of testosterone to DHT, resulting in significant decreases in serum and tissue DHT concentrations. Finasteride produces a rapid reduction in serum DHT concentration, reaching 65% suppression within 24 hours of oral dosing with a 1-mg tablet. Mean circulating levels of testosterone and estradiol were increased by approximately 15% as compared to baseline, but these remained within the physiologic range.

In men with male pattern hair loss (androgenetic alopecia), the balding scalp contains miniaturized hair follicles and increased amounts of DHT compared with hairy scalp. Administration of finasteride decreases scalp and serum DHT concentrations in these men. The relative contributions of these reductions to the treatment effect of finasteride have not been defined. By this mechanism, finasteride

appears to interrupt a key factor in the development of androgenetic alopecia in those patients genetically predisposed.

A 48-week, placebo-controlled study designed to assess by phototrichogram the effect of PROPECIA on total and actively growing (anagen) scalp hairs in vertex baldness enrolled 212 men with androgenetic alopecia. At baseline and 48 weeks, total and anagen hair counts were obtained in a 1-cm^2 target area of the scalp. Men treated with PROPECIA showed increases from baseline in total and anagen hair counts of 7 hairs and 18 hairs, respectively, whereas men treated with placebo had decreases of 10 hairs and 9 hairs, respectively. These changes in hair counts resulted in a between-group difference of 17 hairs in total hair count ($p<0.001$) and 27 hairs in anagen hair count ($p<0.001$), and an improvement in the proportion of anagen hairs from 62% at baseline to 68% for men treated with PROPECIA.

Pharmacokinetics

Absorption

In a study in 15 healthy young male subjects, the mean bioavailability of finasteride 1-mg tablets was 65% (range 26-170%), based on the ratio of area under the curve (AUC) relative to an intravenous (IV) reference dose. At steady state following dosing with 1 mg/day (n=12), maximum finasteride plasma concentration averaged 9.2 ng/mL (range, 4.9-13.7 ng/mL) and was reached 1 to 2 hours postdose; $AUC_{(0\text{-}24\ hr)}$ was 53 ng•hr/mL (range, 20-154 ng•hr/mL). Bioavailability of finasteride was not affected by food.

Distribution

Mean steady-state volume of distribution was 76 liters (range, 44-96 liters; n=15). Approximately 90% of circulating finasteride is bound to plasma proteins. There is a slow accumulation phase for finasteride after multiple dosing.

Finasteride has been found to cross the blood-brain barrier.

Semen levels have been measured in 35 men taking finasteride 1 mg/day for 6 weeks. In 60% (21 of 35) of the samples, finasteride levels were undetectable (<0.2 ng/mL). The mean finasteride level was 0.26 ng/mL and the highest level measured was 1.52 ng/mL. Using the highest semen level measured and assuming 100% absorption from a 5-mL ejaculate per day, human exposure through vaginal absorption would be up to 7.6 ng per day, which is 750 times lower than the exposure from the no-effect dose for developmental abnormalities in Rhesus monkeys and 650-fold less than the dose of finasteride (5 μg) that had no effect on circulating DHT levels in men (see PRECAUTIONS, *Pregnancy*).

Metabolism

Finasteride is extensively metabolized in the liver, primarily via the cytochrome P450 3A4 enzyme subfamily. Two metabolites, the t-butyl side chain monohydroxylated and monocarboxylic acid metabolites, have been identified that possess no more than 20% of the 5α-reductase inhibitory activity of finasteride.

Excretion

Following intravenous infusion in healthy young subjects (n=15), mean plasma clearance of finasteride was 165 mL/min (range, 70-279 mL/min). Mean terminal half-life in plasma was 4.5 hours (range, 3.3-13.4 hours; n=12). Following an oral dose of ^{14}C-finasteride in man (n=6), a mean of 39% (range, 32-46%) of the dose was excreted in the urine in the form of metabolites; 57% (range, 51-64%) was excreted in the feces.

Mean terminal half-life is approximately 5-6 hours in men 18-60 years of age and 8 hours in men more than 70 years of age.

Special Populations

Pediatric: Finasteride pharmacokinetics have not been investigated in patients <18 years of age.

Gender: PROPECIA is not indicated for use in women.

Geriatric: No dosage adjustment is necessary in the elderly. Although the elimination rate of finasteride is decreased in the elderly, these findings are of no clinical significance. See also *Pharmacokinetics, Excretion*, and PRECAUTIONS, *Geriatric Use* sections.

Race: The effect of race on finasteride pharmacokinetics has not been studied.

Renal Insufficiency: No dosage adjustment is necessary in patients with renal insufficiency. In patients with chronic renal impairment, with creatinine clearances ranging from 9.0 to 55 mL/min, AUC, maximum plasma concentration, half-life, and protein binding after a single dose of ^{14}C-finasteride were similar to those obtained in healthy volunteers. Urinary excretion of metabolites was decreased in patients with renal impairment. This decrease was associated with an increase in fecal excretion of metabolites. Plasma concentrations of metabolites were significantly higher in patients with renal impairment (based on a 60% increase in total radioactivity AUC). However, finasteride has been well tolerated in men with normal renal function receiving up to 80 mg/day for 12 weeks where exposure of these patients to metabolites would presumably be much greater.

Hepatic Insufficiency: The effect of hepatic insufficiency on finasteride pharmacokinetics has not been studied. Caution should be used in the administration of PROPECIA in patients with liver function abnormalities, as finasteride is metabolized extensively in the liver.

Drug Interactions (also see PRECAUTIONS, *Drug Interactions*)

No drug interactions of clinical importance have been identified. Finasteride does not appear to affect the cytochrome P450-linked drug-metabolizing enzyme system. Compounds that have been tested in man include antipyrine, digoxin, propranolol, theophylline, and warfarin and no clinically meaningful interactions were found.

Mean (SD) Pharmacokinetic Parameters in Healthy Men (ages 18-26)	
	Mean (± SD) n=15
Bioavailability	65% (26-170%)*
Clearance (mL/min)	165 (55)
Volume of Distribution (L)	76 (14)

*Range

Mean (SD) Noncompartmental Pharmacokinetic Parameters After Multiple Doses of 1 mg/day in Healthy Men (ages 19-42)	
	Mean (± SD) (n=12)
AUC (ng•hr/mL)	53 (33.8)
Peak Concentration (ng/mL)	9.2 (2.6)
Time to Peak (hours)	1.3 (0.5)
Half-Life (hours)*	4.5 (1.6)

*First-dose values; all other parameters are last-dose values

Clinical Studies

Studies in Men

The efficacy of PROPECIA was demonstrated in men (88% Caucasian) with mild to moderate androgenetic alopecia (male pattern hair loss) between 18 and 41 years of age. In order to prevent seborrheic dermatitis which might confound the assessment of hair growth in these studies, all men, whether treated with finasteride or placebo, were instructed to use a specified, medicated, tar-based shampoo (Neutrogena T/Gel®* Shampoo) during the first 2 years of the studies.

There were three double-blind, randomized, placebo-controlled studies of 12-month duration. The two primary endpoints were hair count and patient self-assessment; the two secondary endpoints were investigator assessment and ratings of photographs. In addition, information was collected regarding sexual function (based on a self-administered questionnaire) and non-scalp body hair growth. The three studies were conducted in 1879 men with mild to moderate, but not complete, hair loss. Two of the studies enrolled men with predominantly mild to moderate vertex hair loss (n=1553). The third enrolled men having mild to moderate hair loss in the anterior mid-scalp area with or without vertex balding (n=326).

Studies in Men with Vertex Baldness

Of the men who completed the first 12 months of the two vertex baldness trials, 1215 elected to continue in double-blind, placebo-controlled, 12-month extension studies. There were 547 men receiving PROPECIA for both the initial study and first extension periods (up to 2 years of treatment) and 60 men

*Registered trademark of Johnson & Johnson

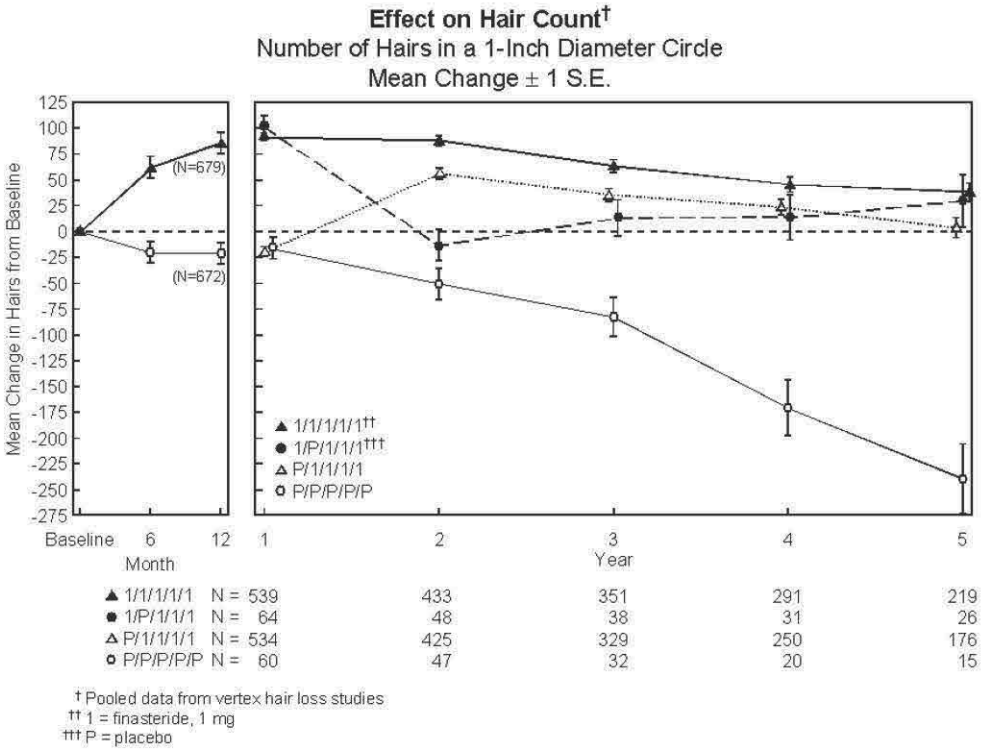
receiving placebo for the same periods. The extension studies were continued for 3 additional years, with 323 men on PROPECIA and 23 on placebo entering the fifth year of the study.

In order to evaluate the effect of discontinuation of therapy, there were 65 men who received PROPECIA for the initial 12 months followed by placebo in the first 12-month extension period. Some of these men continued in additional extension studies and were switched back to treatment with PROPECIA, with 32 men entering the fifth year of the study. Lastly, there were 543 men who received placebo for the initial 12 months followed by PROPECIA in the first 12-month extension period. Some of these men continued in additional extension studies receiving PROPECIA, with 290 men entering the fifth year of the study (see Figure below).

Hair counts were assessed by photographic enlargements of a representative area of active hair loss. In these two studies in men with vertex baldness, significant increases in hair count were demonstrated at 6 and 12 months in men treated with PROPECIA, while significant hair loss from baseline was demonstrated in those treated with placebo. At 12 months there was a 107-hair difference from placebo ($p<0.001$, PROPECIA [n=679] vs placebo [n=672]) within a 1-inch diameter circle (5.1 cm^2). Hair count was maintained in those men taking PROPECIA for up to 2 years, resulting in a 138-hair difference between treatment groups ($p<0.001$, PROPECIA [n=433] vs placebo [n=47]) within the same area. In men treated with PROPECIA, the maximum improvement in hair count compared to baseline was achieved during the first 2 years. Although the initial improvement was followed by a slow decline, hair count was maintained above baseline throughout the 5 years of the studies. Furthermore, because the decline in the placebo group was more rapid, the difference between treatment groups also continued to increase throughout the studies, resulting in a 277-hair difference ($p<0.001$, PROPECIA [n=219] vs placebo [n=15]) at 5 years (see Figure below).

Patients who switched from placebo to PROPECIA (n=425) had a decrease in hair count at the end of the initial 12-month placebo period, followed by an increase in hair count after 1 year of treatment with PROPECIA. This increase in hair count was less (56 hairs above original baseline) than the increase (91 hairs above original baseline) observed after 1 year of treatment in men initially randomized to PROPECIA. Although the increase in hair count, relative to when therapy was initiated, was comparable between these two groups, a higher absolute hair count was achieved in patients who were started on treatment with PROPECIA in the initial study. This advantage was maintained through the remaining 3 years of the studies. A change of treatment from PROPECIA to placebo (n=48) at the end of the initial 12 months resulted in reversal of the increase in hair count 12 months later, at 24 months (see Figure below).

At 12 months, 58% of men in the placebo group had further hair loss (defined as any decrease in hair count from baseline), compared with 14% of men treated with PROPECIA. In men treated for up to 2 years, 72% of men in the placebo group demonstrated hair loss, compared with 17% of men treated with PROPECIA. At 5 years, 100% of men in the placebo group demonstrated hair loss, compared with 35% of men treated with PROPECIA.



Patient self-assessment was obtained at each clinic visit from a self-administered questionnaire, which included questions on their perception of hair growth, hair loss, and appearance. This self-assessment demonstrated an increase in amount of hair, a decrease in hair loss, and improvement in appearance in men treated with PROPECIA. Overall improvement compared with placebo was seen as early as 3 months ($p<0.05$), with improvement maintained over 5 years.

Investigator assessment was based on a 7-point scale evaluating increases or decreases in scalp hair at each patient visit. This assessment showed significantly greater increases in hair growth in men treated with PROPECIA compared with placebo as early as 3 months ($p<0.001$). At 12 months, the investigators rated 65% of men treated with PROPECIA as having increased hair growth compared with 37% in the placebo group. At 2 years, the investigators rated 80% of men treated with PROPECIA as having increased hair growth compared with 47% of men treated with placebo. At 5 years, the investigators rated 77% of men treated with PROPECIA as having increased hair growth, compared with 15% of men treated with placebo.

An independent panel rated standardized photographs of the head in a blinded fashion based on increases or decreases in scalp hair using the same 7-point scale as the investigator assessment. At 12 months, 48% of men treated with PROPECIA had an increase as compared with 7% of men treated with placebo. At 2 years, an increase in hair growth was demonstrated in 66% of men treated with PROPECIA, compared with 7% of men treated with placebo. At 5 years, 48% of men treated with PROPECIA demonstrated an increase in hair growth, 42% were rated as having no change (no further visible progression of hair loss from baseline) and 10% were rated as having lost hair when compared to baseline. In comparison, 6% of men treated with placebo demonstrated an increase in hair growth, 19% were rated as having no change and 75% were rated as having lost hair when compared to baseline.

Other Results in Vertex Baldness Studies

A sexual function questionnaire was self-administered by patients participating in the two vertex baldness trials to detect more subtle changes in sexual function. At Month 12, statistically significant differences in favor of placebo were found in 3 of 4 domains (sexual interest, erections, and perception of sexual problems). However, no significant difference was seen in the question on overall satisfaction with sex life.

In one of the two vertex baldness studies, patients were questioned on non-scalp body hair growth. PROPECIA did not appear to affect non-scalp body hair.

Study in Men with Hair Loss in the Anterior Mid-Scalp Area

A study of 12-month duration, designed to assess the efficacy of PROPECIA in men with hair loss in the anterior mid-scalp area, also demonstrated significant increases in hair count compared with placebo. Increases in hair count were accompanied by improvements in patient self-assessment, investigator assessment, and ratings based on standardized photographs. Hair counts were obtained in the anterior mid-scalp area, and did not include the area of bitemporal recession or the anterior hairline.

Summary of Clinical Studies in Men

Clinical studies were conducted in men aged 18 to 41 with mild to moderate degrees of androgenetic alopecia. All men treated with PROPECIA or placebo received a tar-based shampoo (Neutrogena T/Gel® Shampoo) during the first 2 years of the studies. Clinical improvement was seen as early as 3 months in the patients treated with PROPECIA and led to a net increase in scalp hair count and hair regrowth. In clinical studies for up to 5 years, treatment with PROPECIA slowed the further progression of hair loss observed in the placebo group. In general, the difference between treatment groups continued to increase throughout the 5 years of the studies.

Ethnic Analysis of Clinical Data from Men

In a combined analysis of the two studies on vertex baldness, mean hair count changes from baseline were 91 vs -19 hairs (PROPECIA vs placebo) among Caucasians (n=1185), 49 vs -27 hairs among Blacks (n=84), 53 vs -38 hairs among Asians (n=17), 67 vs 5 hairs among Hispanics (n=45) and 67 vs -15 hairs among other ethnic groups (n=20). Patient self-assessment showed improvement across racial groups with PROPECIA treatment, except for satisfaction of the frontal hairline and vertex in Black men, who were satisfied overall.

Study in Women

In a study involving 137 postmenopausal women with androgenetic alopecia who were treated with PROPECIA (n=67) or placebo (n=70) for 12 months, effectiveness could not be demonstrated. There was no improvement in hair counts, patient self-assessment, investigator assessment, or ratings of standardized photographs in the women treated with PROPECIA when compared with the placebo group (see INDICATIONS AND USAGE).

INDICATIONS AND USAGE

PROPECIA is indicated for the treatment of male pattern hair loss (androgenetic alopecia) in **MEN ONLY**. Safety and efficacy were demonstrated in men between 18 to 41 years of age with mild to moderate hair loss of the vertex and anterior mid-scalp area (see CLINICAL PHARMACOLOGY, *Clinical Studies*).

Efficacy in bitemporal recession has not been established.

PROPECIA is not indicated in women (see CLINICAL PHARMACOLOGY, *Clinical Studies* and CONTRAINDICATIONS).

PROPECIA is not indicated in children (see PRECAUTIONS, *Pediatric Use*).

CONTRAINDICATIONS

PROPECIA is contraindicated in the following:

Pregnancy. Finasteride use is contraindicated in women when they are or may potentially be pregnant. Because of the ability of Type II 5α-reductase inhibitors to inhibit the conversion of testosterone to DHT, finasteride may cause abnormalities of the external genitalia of a male fetus of a pregnant woman who receives finasteride. If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the pregnant woman should be apprised of the potential hazard to the male fetus. (See also WARNINGS, EXPOSURE OF WOMEN - RISK TO MALE FETUS; and PRECAUTIONS, *Information for Patients* and *Pregnancy*.) In female rats, low doses of finasteride administered during pregnancy have produced abnormalities of the external genitalia in male offspring.

Hypersensitivity to any component of this medication.

WARNINGS

PROPECIA is not indicated for use in pediatric patients (see INDICATIONS AND USAGE; and PRECAUTIONS, *Pediatric Use*) or women (see also WARNINGS, EXPOSURE OF WOMEN - RISK TO MALE FETUS; PRECAUTIONS, *Information for Patients* and *Pregnancy;* and HOW SUPPLIED, *Storage and Handling*).

EXPOSURE OF WOMEN - RISK TO MALE FETUS

Women should not handle crushed or broken PROPECIA tablets when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed. (See also CONTRAINDICATIONS; PRECAUTIONS, *Information for Patients* and *Pregnancy;* and HOW SUPPLIED, *Storage and Handling*.)

PRECAUTIONS

General

Caution should be used in the administration of PROPECIA in patients with liver function abnormalities, as finasteride is metabolized extensively in the liver.

Information for Patients

Women should not handle crushed or broken PROPECIA tablets when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed. (See also CONTRAINDICATIONS; WARNINGS, EXPOSURE OF WOMEN - RISK TO MALE FETUS; PRECAUTIONS, *Pregnancy;* and HOW SUPPLIED, *Storage and Handling.*)

Physicians should instruct their patients to promptly report any changes in their breasts such as lumps, pain or nipple discharge. Breast changes including breast enlargement, tenderness and neoplasm have been reported (see ADVERSE REACTIONS).

See also Patient Package Insert.

Physicians should instruct their patients to read the patient package insert before starting therapy with PROPECIA and to read it again each time the prescription is renewed so that they are aware of current information for patients regarding PROPECIA.

Drug/Laboratory Test Interactions

Finasteride had no effect on circulating levels of cortisol, thyroid-stimulating hormone, or thyroxine, nor did it affect the plasma lipid profile (e.g., total cholesterol, low-density lipoproteins, high-density lipoproteins and triglycerides) or bone mineral density. In studies with finasteride, no clinically meaningful changes in luteinizing hormone (LH), follicle-stimulating hormone (FSH) or prolactin were detected. In healthy volunteers, treatment with finasteride did not alter the response of LH and FSH to gonadotropin-releasing hormone indicating that the hypothalamic-pituitary-testicular axis was not affected.

In clinical studies with PROPECIA (finasteride, 1 mg) in men 18-41 years of age, the mean value of serum prostate-specific antigen (PSA) decreased from 0.7 ng/mL at baseline to 0.5 ng/mL at Month 12. Further, in clinical studies with PROSCAR (finasteride, 5 mg) when used in older men who have benign prostatic hyperplasia (BPH), PSA levels are decreased by approximately 50%. Other studies with PROSCAR showed it may also cause decreases in serum PSA in the presence of prostate cancer. These findings should be taken into account for proper interpretation of serum PSA when evaluating men treated with finasteride. Any confirmed increases in PSA levels from nadir while on PROPECIA may signal the presence of prostate cancer and should be carefully evaluated, even if those values are still within the normal range for men not taking a 5α-reductase inhibitor. Non-compliance to therapy with PROPECIA may also affect PSA test results.

Drug Interactions

No drug interactions of clinical importance have been identified. Finasteride does not appear to affect the cytochrome P450-linked drug-metabolizing enzyme system. Compounds that have been tested in man include antipyrine, digoxin, propranolol, theophylline, and warfarin and no clinically meaningful interactions were found.

Other concomitant therapy: Although specific interaction studies were not performed, finasteride doses of 1 mg or more were concomitantly used in clinical studies with acetaminophen, acetylsalicylic acid, α-blockers, analgesics, angiotensin-converting enzyme (ACE) inhibitors, anticonvulsants, benzodiazepines, beta blockers, calcium-channel blockers, cardiac nitrates, diuretics, H_2 antagonists, HMG-CoA reductase inhibitors, prostaglandin synthetase inhibitors (also referred to as NSAIDs), and quinolone anti-infectives without evidence of clinically significant adverse interactions.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No evidence of a tumorigenic effect was observed in a 24-month study in Sprague-Dawley rats receiving doses of finasteride up to 160 mg/kg/day in males and 320 mg/kg/day in females. These doses

produced respective systemic exposure in rats of 888 and 2192 times those observed in man receiving the recommended human dose of 1 mg/day. All exposure calculations were based on calculated $AUC_{(0\text{-}24\ hr)}$ for animals and mean $AUC_{(0\text{-}24\ hr)}$ for man (0.05 μg•hr/mL).

In a 19-month carcinogenicity study in CD-1 mice, a statistically significant ($p \leq 0.05$) increase in the incidence of testicular Leydig cell adenomas was observed at a dose of 250 mg/kg/day (1824 times the human exposure). In mice at a dose of 25 mg/kg/day (184 times the human exposure, estimated) and in rats at a dose of ≥40 mg/kg/day (312 times the human exposure) an increase in the incidence of Leydig cell hyperplasia was observed. A positive correlation between the proliferative changes in the Leydig cells and an increase in serum LH levels (2- to 3-fold above control) has been demonstrated in both rodent species treated with high doses of finasteride. No drug-related Leydig cell changes were seen in either rats or dogs treated with finasteride for 1 year at doses of 20 mg/kg/day and 45 mg/kg/day (240 and 2800 times, respectively, the human exposure) or in mice treated for 19 months at a dose of 2.5 mg/kg/day (18.4 times the human exposure, estimated).

No evidence of mutagenicity was observed in an *in vitro* bacterial mutagenesis assay, a mammalian cell mutagenesis assay, or in an *in vitro* alkaline elution assay. In an *in vitro* chromosome aberration assay, using Chinese hamster ovary cells, there was a slight increase in chromosome aberrations. In an *in vivo* chromosome aberration assay in mice, no treatment-related increase in chromosome aberration was observed with finasteride at the maximum tolerated dose of 250 mg/kg/day (1824 times the human exposure) as determined in the carcinogenicity studies.

In sexually mature male rabbits treated with finasteride at 80 mg/kg/day (4344 times the human exposure) for up to 12 weeks, no effect on fertility, sperm count, or ejaculate volume was seen. In sexually mature male rats treated with 80 mg/kg/day of finasteride (488 times the human exposure), there were no significant effects on fertility after 6 or 12 weeks of treatment; however, when treatment was continued for up to 24 or 30 weeks, there was an apparent decrease in fertility, fecundity, and an associated significant decrease in the weights of the seminal vesicles and prostate. All these effects were reversible within 6 weeks of discontinuation of treatment. No drug-related effect on testes or on mating performance has been seen in rats or rabbits. This decrease in fertility in finasteride-treated rats is secondary to its effect on accessory sex organs (prostate and seminal vesicles) resulting in failure to form a seminal plug. The seminal plug is essential for normal fertility in rats but is not relevant in man.

Pregnancy

Teratogenic Effects: Pregnancy Category X

See CONTRAINDICATIONS.

PROPECIA is not indicated for use in women.

Administration of finasteride to pregnant rats on gestational days 6-20 at doses ranging from 100 μg/kg/day to 100 mg/kg/day (1-684 times the human exposure, estimated) resulted in dose-dependent development of hypospadias in 3.6 to 100% of male offspring. Pregnant rats produced male offspring with decreased prostatic and seminal vesicular weights, delayed preputial separation, and transient nipple development when given finasteride at ≥30 μg/kg/day (0.2 times the human exposure, estimated) and decreased anogenital distance when given finasteride at ≥3 μg/kg/day (0.02 times the human exposure, estimated). The critical period during which these effects can be induced in male rats has been defined to be days 16-17 of gestation. The changes described above are expected pharmacological effects of drugs belonging to the class of Type II 5α-reductase inhibitors and are similar to those reported in male infants with a genetic deficiency of Type II 5α-reductase. No abnormalities were observed in female offspring exposed to any dose of finasteride *in utero*.

No developmental abnormalities have been observed in first filial generation (F_1) male or female offspring resulting from mating finasteride-treated male rats (80 mg/kg/day; 488 times the human exposure) with untreated females. Administration of finasteride at 3 mg/kg/day (20 times the human exposure, estimated) during the late gestation and lactation period resulted in slightly decreased fertility in F_1 male offspring. No effects were seen in female offspring.

No evidence of malformations has been observed in rabbit fetuses exposed to finasteride *in utero* from days 6-18 of gestation at doses up to 100 mg/kg/day (1908 times the recommended human dose of 1 mg/day, based on body surface area comparison). However, effects on male genitalia would not be expected since the rabbits were not exposed during the critical period of genital system development.

The *in utero* effects of finasteride exposure during the period of embryonic and fetal development were evaluated in the rhesus monkey (gestation days 20-100), a species more predictive of human development than rats or rabbits. Intravenous administration of finasteride to pregnant monkeys at doses up to 800 ng/day (at least 250 times the highest estimated exposure of pregnant women to finasteride

from semen of men taking 1 mg/day, based on body surface area comparison) resulted in no abnormalities in male fetuses. In confirmation of the relevance of the rhesus model for human fetal development, oral administration of a 2 mg/kg/day dose of finasteride to pregnant monkeys resulted in external genital abnormalities in male fetuses. No other abnormalities were observed in male fetuses and no finasteride-related abnormalities were observed in female fetuses at any dose.

Nursing Mothers

PROPECIA is not indicated for use in women.

It is not known whether finasteride is excreted in human milk.

Pediatric Use

PROPECIA is not indicated for use in pediatric patients.

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Clinical efficacy studies with PROPECIA did not include subjects aged 65 and over. Based on the pharmacokinetics of finasteride 5 mg, no dosage adjustment is necessary in the elderly for PROPECIA (see CLINICAL PHARMACOLOGY, *Pharmacokinetics*). However the efficacy of PROPECIA in the elderly has not been established.

ADVERSE REACTIONS

Clinical Studies for PROPECIA (finasteride 1 mg) in the Treatment of Male Pattern Hair Loss

In three controlled clinical trials for PROPECIA of 12-month duration, 1.4% of patients taking PROPECIA (n=945) were discontinued due to adverse experiences that were considered to be possibly, probably or definitely drug-related (1.6% for placebo; n=934).

Clinical adverse experiences that were reported as possibly, probably or definitely drug-related in ≥1% of patients treated with PROPECIA or placebo are presented in Table 1.

TABLE 1
Drug-Related Adverse Experiences for PROPECIA (finasteride 1 mg) in Year 1 (%)
MALE PATTERN HAIR LOSS

	PROPECIA N=945	Placebo N=934
Decreased Libido	1.8	1.3
Erectile Dysfunction	1.3	0.7
Ejaculation Disorder *(Decreased Volume of Ejaculate)*	1.2 *(0.8)*	0.7 *(0.4)*
Discontinuation due to drug-related sexual adverse experiences	1.2	0.9

Integrated analysis of clinical adverse experiences showed that during treatment with PROPECIA, 36 (3.8%) of 945 men had reported one or more of these adverse experiences as compared to 20 (2.1%) of 934 men treated with placebo (p=0.04). Resolution occurred in men who discontinued therapy with PROPECIA due to these side effects and in most of those who continued therapy. The incidence of each of the above adverse experiences decreased to ≤0.3% by the fifth year of treatment with PROPECIA.

In a study of finasteride 1 mg daily in healthy men, a median decrease in ejaculate volume of 0.3 mL (-11%) compared with 0.2 mL (–8%) for placebo was observed after 48 weeks of treatment. Two other studies showed that finasteride at 5 times the dosage of PROPECIA (5 mg daily) produced significant median decreases of approximately 0.5 mL (-25%) compared to placebo in ejaculate volume, but this was reversible after discontinuation of treatment.

In the clinical studies with PROPECIA, the incidences for breast tenderness and enlargement, hypersensitivity reactions, and testicular pain in finasteride-treated patients were not different from those in patients treated with placebo.

Postmarketing Experience for PROPECIA (finasteride 1 mg)

Breast tenderness and enlargement; depression; hypersensitivity reactions including rash, pruritus, urticaria, and swelling of the lips and face; testicular pain; and male breast cancer. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure. See *Controlled Clinical Trials and Long-Term Open Extension Studies for PROSCAR® (finasteride 5 mg) in the Treatment of Benign Prostatic Hyperplasia*.

Controlled Clinical Trials and Long-Term Open Extension Studies for PROSCAR® (finasteride 5 mg) in the Treatment of Benign Prostatic Hyperplasia

In the PROSCAR Long-Term Efficacy and Safety Study (PLESS), a 4-year controlled clinical study, 3040 patients between the ages of 45 and 78 with symptomatic BPH and an enlarged prostate were evaluated for safety over a period of 4 years (1524 on PROSCAR 5 mg/day and 1516 on placebo). 3.7% (57 patients) treated with PROSCAR 5 mg and 2.1% (32 patients) treated with placebo discontinued therapy as a result of adverse reactions related to sexual function, which are the most frequently reported adverse reactions.

Table 2 presents the only clinical adverse reactions considered possibly, probably or definitely drug related by the investigator, for which the incidence on PROSCAR was ≥1% and greater than placebo over the 4 years of the study. In years 2-4 of the study, there was no significant difference between treatment groups in the incidences of impotence, decreased libido and ejaculation disorder.

TABLE 2
Drug-Related Adverse Experiences for PROSCAR (finasteride 5 mg)
BENIGN PROSTATIC HYPERPLASIA

	Year 1 (%)		Years 2, 3 and 4* (%)	
	Finasteride, 5 mg	Placebo	Finasteride, 5 mg	Placebo
Impotence	8.1	3.7	5.1	5.1
Decreased Libido	6.4	3.4	2.6	2.6
Decreased Volume of Ejaculate	3.7	0.8	1.5	0.5
Ejaculation Disorder	0.8	0.1	0.2	0.1
Breast Enlargement	0.5	0.1	1.8	1.1
Breast Tenderness	0.4	0.1	0.7	0.3
Rash	0.5	0.2	0.5	0.1

*Combined Years 2-4
N = 1524 and 1516, finasteride vs placebo, respectively

The adverse experience profiles in the 1-year, placebo-controlled, Phase III BPH studies and the 5-year open extensions with PROSCAR 5 mg and PLESS were similar.

There is no evidence of increased adverse experiences with increased duration of treatment with PROSCAR 5 mg. New reports of drug-related sexual adverse experiences decreased with duration of therapy.

The relationship between long-term use of finasteride and male breast neoplasia is currently unknown. During a 4- to 6-year placebo- and comparator-controlled study that enrolled 3047 men, there were 4 cases of breast cancer in men treated with PROSCAR but no cases in men not treated with PROSCAR. In another 4-year, placebo-controlled study that enrolled 3040 men, there were 2 cases of breast cancer in placebo-treated men, but no cases were reported in men treated with PROSCAR.

In a 7-year placebo-controlled trial that enrolled 18,882 healthy men, 9060 had prostate needle biopsy data available for analysis. In the PROSCAR group, 280 (6.4%) men had prostate cancer with Gleason scores of 7-10 detected on needle biopsy vs. 237 (5.1%) men in the placebo group. Of the total cases of prostate cancer diagnosed in this study, approximately 98% were classified as intracapsular (stage T1 or T2). The clinical significance of these findings is unknown. This information from the literature (Thompson IM, Goodman PJ, Tangen CM, et al. The influence of finasteride on the development of prostate cancer. *N Engl J Med* 2003;349:213-22) is provided for consideration by physicians when PROSCAR is used as indicated. PROSCAR is not approved to reduce the risk of developing prostate cancer.

OVERDOSAGE

In clinical studies, single doses of finasteride up to 400 mg and multiple doses of finasteride up to 80 mg/day for three months did not result in adverse reactions. Until further experience is obtained, no specific treatment for an overdose with finasteride can be recommended.

Significant lethality was observed in male and female mice at single oral doses of 1500 mg/m^2 (500 mg/kg) and in female and male rats at single oral doses of 2360 mg/m^2 (400 mg/kg) and 5900 mg/m^2 (1000 mg/kg), respectively.

DOSAGE AND ADMINISTRATION

The recommended dosage is 1 mg orally once a day.

PROPECIA may be administered with or without meals.

In general, daily use for three months or more is necessary before benefit is observed. Continued use is recommended to sustain benefit, which should be re-evaluated periodically. Withdrawal of treatment leads to reversal of effect within 12 months.

HOW SUPPLIED

No. 6642 — PROPECIA tablets, 1 mg, are tan, octagonal, film-coated convex tablets with "stylized P" logo on one side and PROPECIA on the other. They are supplied as follows:

NDC 0006-0071-31 unit of use bottles of 30 (with desiccant)

NDC 0006-0071-54 PROPAK® - unit of use bottles of 90 (with desiccant).

Storage and Handling

Store at room temperature, 15-30°C (59-86°F). Keep container closed and protect from moisture.

Women should not handle crushed or broken PROPECIA tablets when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets are not broken or crushed. (See WARNINGS, EXPOSURE OF WOMEN - RISK TO MALE FETUS; and PRECAUTIONS, *Information for Patients* and *Pregnancy*.)

Dist. by: Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC., Whitehouse Station, NJ 08889, USA

Issued December 2010

US Patent Nos.: 5,547,957; 5,571,817

PROPECIA®
(finasteride) Tablets, 1 mg
Patient Information about
PROPECIA® (Pro-pee-sha)

Generic name: finasteride
(fin-AS-tur-eyed)

PROPECIA® is for use by MEN ONLY.

Please read this leaflet before you start taking PROPECIA. Also, read the information included with PROPECIA each time you renew your prescription, just in case anything has changed. Remember, this leaflet does not take the place of careful discussions with your doctor. You and your doctor should discuss PROPECIA when you start taking your medication and at regular checkups.

What is PROPECIA used for?

PROPECIA is used for the treatment of male pattern hair loss on the vertex and the anterior mid-scalp area.

PROPECIA is for use by **MEN ONLY** and should **NOT** be used by women or children.

What is male pattern hair loss?

Male pattern hair loss is a common condition in which men experience thinning of the hair on the scalp. Often, this results in a receding hairline and/or balding on the top of the head. These changes typically begin gradually in men in their 20s.

Doctors believe male pattern hair loss is due to heredity and is dependent on hormonal effects. Doctors refer to this type of hair loss as androgenetic alopecia.

Results of clinical studies:

For 12 months, doctors studied over 1800 men aged 18 to 41 with mild to moderate amounts of ongoing hair loss. Of these men, approximately 1200 with hair loss at the top of the head participated in additional extension studies, resulting in a total study time of up to five years. In general, men who took PROPECIA maintained or increased the number of visible scalp hairs and noticed improvement in their hair in the first year. Improvement, compared to the start of the study, was maintained through the remaining years of treatment. Hair counts in men who did not take PROPECIA continued to decrease.

In one study, patients were questioned on the growth of body hair. PROPECIA did not appear to affect hair in places other than the scalp.

Will PROPECIA work for me?

For most men, PROPECIA increases the number of scalp hairs in the first year of treatment, helping to fill in thin or balding areas of the scalp. In addition, men taking PROPECIA may note a slowing of hair loss. Although results will vary, generally you will not be able to grow back all of the hair you have lost. There is not sufficient evidence that PROPECIA works in the treatment of receding hairline in the temporal area on both sides of the head.

Male pattern hair loss occurs gradually over time. On average, healthy hair grows only about half an inch each month. Therefore, it will take time to see any effect.

You may need to take PROPECIA daily for three months or more before you see a benefit from taking PROPECIA. PROPECIA can only work over the long term if you continue taking it. If the drug has not worked for you in twelve months, further treatment is unlikely to be of benefit. If you stop taking PROPECIA, you will likely lose the hair you have gained within 12 months of stopping treatment. You should discuss this with your doctor.

PROPECIA is not effective in the treatment of hair loss due to androgenetic alopecia in postmenopausal women. PROPECIA should not be taken by women.

How should I take PROPECIA?

Follow your doctor's instructions.

- Take one tablet by mouth each day.
- You may take PROPECIA with or without food.
- If you forget to take PROPECIA, do not take an extra tablet. Just take the next tablet as usual.

PROPECIA will not work faster or better if you take it more than once a day.

Who should NOT take PROPECIA?

- PROPECIA is for the treatment of male pattern hair loss in **MEN ONLY** and should not be taken by women (see **A warning about PROPECIA and pregnancy**).
- PROPECIA should not be taken by children.
- Anyone allergic to any of the ingredients.

A warning about PROPECIA and pregnancy.

- **Women who are or may potentially be pregnant:**

  -must not use PROPECIA

  -should not handle crushed or broken tablets of PROPECIA.

If a woman who is pregnant with a male baby absorbs the active ingredient in PROPECIA, either by swallowing or through the skin, it may cause abnormalities of a male baby's sex organs. If a woman who is pregnant comes into contact with the active ingredient in PROPECIA, a doctor should be consulted. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets are not broken or crushed.

What are the possible side effects of PROPECIA?

Like all prescription products, PROPECIA may cause side effects. In clinical studies, side effects from PROPECIA were uncommon and did not affect most men. A small number of men experienced certain sexual side effects. These men reported one or more of the following: less desire for sex; difficulty in achieving an erection; and, a decrease in the amount of semen. Each of these side effects occurred in less than 2% of men. These side effects went away in men who stopped taking PROPECIA. They also disappeared in most men who continued taking PROPECIA.

In general use, the following have been reported: breast tenderness and enlargement; depression; allergic reactions including rash, itching, hives and swelling of the lips and face; problems with ejaculation; testicular pain; and, in rare cases, male breast cancer. You should promptly report to your doctor any changes in your breasts such as lumps, pain or nipple discharge. Tell your doctor promptly about these or any other unusual side effects.

- **PROPECIA can affect a blood test called PSA (Prostate-Specific Antigen) for the screening of prostate cancer. If you have a PSA test done, you should tell your doctor(s) that you are taking PROPECIA. Because PROPECIA decreases PSA levels, changes in PSA levels will need to be carefully evaluated by your doctor(s). Any increase in follow-up PSA levels from their lowest point should be carefully evaluated even if the test results are still within the normal range for men not taking PROPECIA. You should also tell your doctor if you have not been taking**

PROPECIA as prescribed because this may affect the PSA test results. For more information, talk to your doctor.

Storage and handling.

Keep PROPECIA in the original container and keep the container closed. Store it in a dry place at room temperature. **PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets are not broken or crushed.**

Do not give your PROPECIA tablets to anyone else. It has been prescribed only for you. Keep PROPECIA and all medications out of the reach of children.

THIS LEAFLET PROVIDES A SUMMARY OF INFORMATION ABOUT PROPECIA. IF AFTER READING THIS LEAFLET YOU HAVE ANY QUESTIONS OR ARE NOT SURE ABOUT ANYTHING, TALK TO YOUR DOCTOR, PHARMACIST, OR HEALTH CARE PROVIDER.

1-888-637-2522, Monday through Friday, 8:30 A.M. TO 7:00 P.M. (ET).

www.propecia.com

Dist. by: Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC., Whitehouse Station, NJ 08889, USA

Issued December 2010

US Patent Nos.: 5,547,957; 5,571,817

EXHIBIT B

Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC.
Whitehouse Station, NJ 08889, USA

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PROPECIA safely and effectively. See full prescribing information for PROPECIA.

PROPECIA® (finasteride) tablets for oral use
Initial U.S. Approval: 1992

RECENT MAJOR CHANGES
Warnings and Precautions, Increased Risk of High-Grade Prostate Cancer with 5α-Reductase Inhibitors (5.3) 06/2011

INDICATIONS AND USAGE
- PROPECIA is a 5α-reductase inhibitor indicated for the treatment of male pattern hair loss (androgenetic alopecia) in **MEN ONLY** (1).
- PROPECIA is not indicated for use in women (1, 4, 5.1).

DOSAGE AND ADMINISTRATION
- PROPECIA may be administered with or without meals (2).
- One tablet (1 mg) taken once daily (2.1).
- In general, daily use for three months or more is necessary before benefit is observed (2.2).

DOSAGE FORMS AND STRENGTHS
1 mg tablets (3).

CONTRAINDICATIONS
- Pregnancy (4, 5.1, 8.1, 16).
- Hypersensitivity to any components of this product (4).

WARNINGS AND PRECAUTIONS
- PROPECIA is not indicated for use in women or pediatric patients (5.1, 5.4).
- Women should not handle crushed or broken PROPECIA tablets when they are pregnant or may potentially be pregnant due to potential risk to a male fetus (5.1, 8.1, 16).
- PROPECIA causes a decrease in serum PSA levels. Any confirmed increase in PSA while on PROPECIA may signal the presence of prostate cancer and should be evaluated, even if those values are still within the normal range for men not taking a 5α-reductase inhibitor (5.2).
- 5α-reductase inhibitors may increase the risk of high-grade prostate cancer (5.3, 6.1).

ADVERSE REACTIONS
The most common adverse reactions, reported in ≥1% of patients treated with PROPECIA and greater than in patients treated with placebo are: decreased libido, erectile dysfunction and ejaculation disorder (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 04/2012

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

PROPECIA® is indicated for the treatment of male pattern hair loss (androgenetic alopecia) in **MEN ONLY**.

Efficacy in bitemporal recession has not been established.

PROPECIA is not indicated for use in women.

2 DOSAGE AND ADMINISTRATION

PROPECIA may be administered with or without meals.

The recommended dose of PROPECIA is one tablet (1 mg) taken once daily.

In general, daily use for three months or more is necessary before benefit is observed. Continued use is recommended to sustain benefit, which should be re-evaluated periodically. Withdrawal of treatment leads to reversal of effect within 12 months.

3 DOSAGE FORMS AND STRENGTHS

PROPECIA tablets (1 mg) are tan, octagonal, film-coated convex tablets with "stylized P" logo on one side and PROPECIA on the other.

4 CONTRAINDICATIONS

PROPECIA is contraindicated in the following:

- Pregnancy. Finasteride use is contraindicated in women when they are or may potentially be pregnant. Because of the ability of Type II 5α-reductase inhibitors to inhibit the conversion of testosterone to 5α-dihydrotestosterone (DHT), finasteride may cause abnormalities of the external genitalia of a male fetus of a pregnant woman who receives finasteride. If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the pregnant woman should be apprised of the potential hazard to the male fetus. [*See Warnings and Precautions (5.1), Use in Specific Populations (8.1), How Supplied/Storage and Handling (16) and Patient Counseling Information (17.1).*] In female rats, low doses of finasteride administered during pregnancy have produced abnormalities of the external genitalia in male offspring.
- Hypersensitivity to any component of this medication.

5 WARNINGS AND PRECAUTIONS

5.1 Exposure of Women — Risk to Male Fetus

PROPECIA is not indicated for use in women. Women should not handle crushed or broken PROPECIA tablets when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed. [S*ee Indications and Usage (1), Contraindications (4), Use in Specific Populations (8.1), How Supplied/Storage and Handling (16) and Patient Counseling Information (17.1).*]

5.2 Effects on Prostate Specific Antigen (PSA)

In clinical studies with PROPECIA (finasteride, 1 mg) in men 18-41 years of age, the mean value of serum prostate specific antigen (PSA) decreased from 0.7 ng/mL at baseline to 0.5 ng/mL at Month 12. Further, in clinical studies with PROSCAR (finasteride, 5 mg) when used in older men who have benign prostatic hyperplasia (BPH), PSA levels are decreased by approximately 50%. Other studies with PROSCAR showed it may also cause decreases in serum PSA in the presence of prostate cancer. These findings should be taken into account for proper interpretation of serum PSA when evaluating men treated with finasteride. Any confirmed increase from the lowest PSA value while on PROPECIA may signal the presence of prostate cancer and should be evaluated, even if PSA levels are still within the normal range for men not taking a 5α-reductase inhibitor. Non-compliance to therapy with PROPECIA may also affect PSA test results.

5.3 Increased Risk of High-Grade Prostate Cancer with 5α-Reductase Inhibitors

Men aged 55 and over with a normal digital rectal examination and PSA ≤3.0 ng/mL at baseline taking finasteride 5 mg/day (5 times the dose of PROPECIA) in the 7-year Prostate Cancer Prevention Trial (PCPT) had an increased risk of Gleason score 8-10 prostate cancer (finasteride 1.8% vs placebo 1.1%). [*See Adverse Reactions (6.1).*] Similar results were observed in a 4-year placebo-controlled clinical trial with another 5α-reductase inhibitor (dutasteride, AVODART) (1% dutasteride vs 0.5% placebo). 5α-reductase inhibitors may increase the risk of development of high-grade prostate cancer. Whether the effect of 5α-reductase inhibitors to reduce prostate volume, or study-related factors, impacted the results of these studies has not been established.

5.4 Pediatric Patients

PROPECIA is not indicated for use in pediatric patients [*see Use in Specific Populations (8.4)*].

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Clinical Studies for PROPECIA (finasteride 1 mg) in the Treatment of Male Pattern Hair Loss

In three controlled clinical trials for PROPECIA of 12-month duration, 1.4% of patients taking PROPECIA (n=945) were discontinued due to adverse experiences that were considered to be possibly, probably or definitely drug-related (1.6% for placebo; n=934).

Clinical adverse experiences that were reported as possibly, probably or definitely drug-related in ≥1% of patients treated with PROPECIA or placebo are presented in Table 1.

TABLE 1
Drug-Related Adverse Experiences for PROPECIA (finasteride 1 mg) in Year 1 (%)
MALE PATTERN HAIR LOSS

	PROPECIA N=945	Placebo N=934
Decreased Libido	1.8	1.3
Erectile Dysfunction	1.3	0.7
Ejaculation Disorder *(Decreased Volume of Ejaculate)*	1.2 *(0.8)*	0.7 *(0.4)*
Discontinuation due to drug-related sexual adverse experiences	1.2	0.9

Integrated analysis of clinical adverse experiences showed that during treatment with PROPECIA, 36 (3.8%) of 945 men had reported one or more of these adverse experiences as compared to 20 (2.1%) of 934 men treated with placebo (p=0.04). Resolution occurred in men who discontinued therapy with PROPECIA due to these side effects and in most of those who continued therapy. The incidence of each of the above adverse experiences decreased to ≤0.3% by the fifth year of treatment with PROPECIA.

In a study of finasteride 1 mg daily in healthy men, a median decrease in ejaculate volume of 0.3 mL (-11%) compared with 0.2 mL (-8%) for placebo was observed after 48 weeks of treatment. Two other studies showed that finasteride at 5 times the dosage of PROPECIA (5 mg daily) produced significant median decreases of approximately 0.5 mL (-25%) compared to placebo in ejaculate volume, but this was reversible after discontinuation of treatment.

In the clinical studies with PROPECIA, the incidences for breast tenderness and enlargement, hypersensitivity reactions, and testicular pain in finasteride-treated patients were not different from those in patients treated with placebo.

Controlled Clinical Trials and Long-Term Open Extension Studies for PROSCAR® (finasteride 5 mg) and AVODART (dutasteride) in the Treatment of Benign Prostatic Hyperplasia

In the PROSCAR Long-Term Efficacy and Safety Study (PLESS), a 4-year controlled clinical study, 3040 patients between the ages of 45 and 78 with symptomatic BPH and an enlarged prostate were evaluated for safety over a period of 4 years (1524 on PROSCAR 5 mg/day and 1516 on placebo). 3.7% (57 patients) treated with PROSCAR 5 mg and 2.1% (32 patients) treated with placebo discontinued therapy as a result of adverse reactions related to sexual function, which are the most frequently reported adverse reactions.

Table 2 presents the only clinical adverse reactions considered possibly, probably or definitely drug related by the investigator, for which the incidence on PROSCAR was ≥1% and greater than placebo over the 4 years of the study. In years 2-4 of the study, there was no significant difference between treatment groups in the incidences of impotence, decreased libido and ejaculation disorder.

TABLE 2
Drug-Related Adverse Experiences for PROSCAR (finasteride 5 mg)
BENIGN PROSTATIC HYPERPLASIA

	Year 1 (%)		Years 2, 3 and 4* (%)	
	Finasteride, 5 mg	Placebo	Finasteride, 5 mg	Placebo
Impotence	8.1	3.7	5.1	5.1
Decreased Libido	6.4	3.4	2.6	2.6
Decreased Volume of Ejaculate	3.7	0.8	1.5	0.5
Ejaculation Disorder	0.8	0.1	0.2	0.1
Breast Enlargement	0.5	0.1	1.8	1.1
Breast Tenderness	0.4	0.1	0.7	0.3
Rash	0.5	0.2	0.5	0.1

*Combined Years 2-4
N = 1524 and 1516, finasteride vs placebo, respectively

The adverse experience profiles in the 1-year, placebo-controlled, Phase III BPH studies and the 5-year open extensions with PROSCAR 5 mg and PLESS were similar.

There is no evidence of increased sexual adverse experiences with increased duration of treatment with PROSCAR 5 mg. New reports of drug-related sexual adverse experiences decreased with duration of therapy.

During the 4- to 6-year placebo- and comparator-controlled Medical Therapy of Prostatic Symptoms (MTOPS) study that enrolled 3047 men, there were 4 cases of breast cancer in men treated with PROSCAR but no cases in men not treated with PROSCAR. During the 4-year placebo-controlled PLESS study that enrolled 3040 men, there were 2 cases of breast cancer in placebo-treated men, but no cases were reported in men treated with PROSCAR.

During the 7-year placebo-controlled Prostate Cancer Prevention Trial (PCPT) that enrolled 18,882 men, there was 1 case of breast cancer in men treated with PROSCAR, and 1 case of breast cancer in men treated with placebo. The relationship between long-term use of finasteride and male breast neoplasia is currently unknown.

The PCPT trial was a 7-year randomized, double-blind, placebo-controlled trial that enrolled 18,882 healthy men ≥55 years of age with a normal digital rectal examination and a PSA ≤3.0 ng/mL. Men received either PROSCAR (finasteride 5 mg) or placebo daily. Patients were evaluated annually with PSA and digital rectal exams. Biopsies were performed for elevated PSA, an abnormal digital rectal exam, or the end of study. The incidence of Gleason score 8-10 prostate cancer was higher in men treated with finasteride (1.8%) than in those treated with placebo

(1.1%). In a 4-year placebo-controlled clinical trial with another 5α-reductase inhibitor [AVODART (dutasteride)], similar results for Gleason score 8-10 prostate cancer were observed (1% dutasteride vs 0.5% placebo). The clinical significance of these findings with respect to use of PROPECIA by men is unknown.

No clinical benefit has been demonstrated in patients with prostate cancer treated with PROSCAR. PROSCAR is not approved to reduce the risk of developing prostate cancer.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post approval use of PROPECIA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

Hypersensitivity Reaction: hypersensitivity reactions including rash, pruritus, urticaria, and swelling of the lips and face;

Reproductive System: sexual dysfunction that continued after discontinuation of treatment, including erectile dysfunction, libido disorders, ejaculation disorders, and orgasm disorders; male infertility and/or poor seminal quality (normalization or improvement of seminal quality has been reported after discontinuation of finasteride); testicular pain. [*See Adverse Reactions (6.1).*]

Neoplasms: male breast cancer;

Breast disorders: breast tenderness and enlargement;

Nervous System/Psychiatric: depression

7 DRUG INTERACTIONS

7.1 Cytochrome P450-Linked Drug Metabolizing Enzyme System

No drug interactions of clinical importance have been identified. Finasteride does not appear to affect the cytochrome P450-linked drug-metabolizing enzyme system. Compounds that have been tested in man include antipyrine, digoxin, propranolol, theophylline, and warfarin and no clinically meaningful interactions were found.

7.2 Other Concomitant Therapy

Although specific interaction studies were not performed, finasteride doses of 1 mg or more were concomitantly used in clinical studies with acetaminophen, acetylsalicylic acid, α-blockers, analgesics, angiotensin-converting enzyme (ACE) inhibitors, anticonvulsants, benzodiazepines, beta blockers, calcium-channel blockers, cardiac nitrates, diuretics, H_2 antagonists, HMG-CoA reductase inhibitors, prostaglandin synthetase inhibitors (also referred to as NSAIDs), and quinolone anti-infectives without evidence of clinically significant adverse interactions.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category X [*see Contraindications (4)*].

PROPECIA is contraindicated for use in women who are or may become pregnant. PROPECIA is a Type II 5α-reductase inhibitor that prevents conversion of testosterone to 5α-dihydrotestosterone (DHT), a hormone necessary for normal development of male genitalia. In animal studies, finasteride caused abnormal development of external genitalia in male fetuses. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the male fetus.

Abnormal male genital development is an expected consequence when conversion of testosterone to 5α-dihydrotestosterone (DHT) is inhibited by 5α-reductase inhibitors. These outcomes are similar to those reported in male infants with genetic 5α-reductase deficiency. Women could be exposed to finasteride through contact with crushed or broken PROPECIA tablets or semen from a male partner taking PROPECIA. With regard to finasteride exposure through the skin, PROPECIA tablets are coated and will prevent skin contact with finasteride during normal handling if the tablets have not been crushed or broken. Women who are pregnant or may become pregnant

should not handle crushed or broken PROPECIA tablets because of possible exposure of a male fetus. If a pregnant woman comes in contact with crushed or broken PROPECIA tablets, the contact area should be washed immediately with soap and water. With regard to potential finasteride exposure through semen, a study has been conducted in men receiving PROPECIA 1 mg/day that measured finasteride concentrations in semen [*see Clinical Pharmacology (12.3)*].

In an embryo-fetal development study, pregnant rats received finasteride during the period of major organogenesis (gestation days 6 to 17). At maternal doses of oral finasteride approximately 1 to 684 times the recommended human dose (RHD) of 1 mg/day (based on AUC at animal doses of 0.1 to 100 mg/kg/day) there was a dose-dependent increase in hypospadias that occurred in 3.6 to 100% of male offspring. Exposure multiples were estimated using data from nonpregnant rats. Days 16 to 17 of gestation is a critical period in male fetal rats for differentiation of the external genitalia. At oral maternal doses approximately 0.2 times the RHD (based on AUC at animal dose of 0.03 mg/kg/day), male offspring had decreased prostatic and seminal vesicular weights, delayed preputial separation and transient nipple development. Decreased anogenital distance occurred in male offspring of pregnant rats that received approximately 0.02 times the RHD (based on AUC at animal dose of 0.003 mg/kg/day). No abnormalities were observed in female offspring exposed to any dose of finasteride *in utero*.

No developmental abnormalities were observed in the offspring of untreated females mated with finasteride-treated male rats that received approximately 488 times the RHD (based on AUC at animal dose of 80 mg/kg/day). Slightly decreased fertility was observed in male offspring after administration of about 20 times the RHD (based on AUC at animal dose of 3 mg/kg/day) to female rats during late gestation and lactation. No effects on fertility were seen in female offspring under these conditions.

No evidence of male external genital malformations or other abnormalities were observed in rabbit fetuses exposed to finasteride during the period of major organogenesis (gestation days 6-18) at maternal doses up to 100 mg/kg/day (finasteride exposure levels were not measured in rabbits). However, this study may not have included the critical period for finasteride effects on development of male external genitalia in the rabbit.

The fetal effects of maternal finasteride exposure during the period of embryonic and fetal development were evaluated in the rhesus monkey (gestation days 20-100), in a species and development period more predictive of specific effects in humans than the studies in rats and rabbits. Intravenous administration of finasteride to pregnant monkeys at doses as high as 800 ng/day (estimated maximal blood concentration of 1.86 ng/mL or about 930 times the highest estimated exposure of pregnant women to finasteride from semen of men taking 1 mg/day) resulted in no abnormalities in male fetuses. In confirmation of the relevance of the rhesus model for human fetal development, oral administration of a dose of finasteride (2 mg/kg/day or approximately 120,000 times the highest estimated blood levels of finasteride from semen of men taking 1 mg/day) to pregnant monkeys resulted in external genital abnormalities in male fetuses. No other abnormalities were observed in male fetuses and no finasteride-related abnormalities were observed in female fetuses at any dose.

8.3 Nursing Mothers

PROPECIA is not indicated for use in women.

It is not known whether finasteride is excreted in human milk.

8.4 Pediatric Use

PROPECIA is not indicated for use in pediatric patients.

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical efficacy studies with PROPECIA did not include subjects aged 65 and over. Based on the pharmacokinetics of finasteride 5 mg, no dosage adjustment is necessary in the elderly for PROPECIA [*see Clinical Pharmacology (12.3)*]. However the efficacy of PROPECIA in the elderly has not been established.

8.6 Hepatic Impairment
Caution should be exercised in the administration of PROPECIA in those patients with liver function abnormalities, as finasteride is metabolized extensively in the liver [*see Clinical Pharmacology (12.3)*].

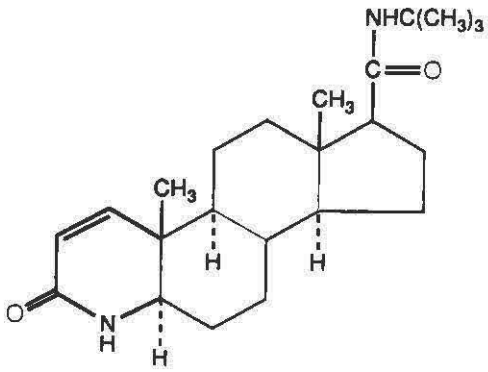
8.7 Renal Impairment
No dosage adjustment is necessary in patients with renal impairment [*see Clinical Pharmacology (12.3)*].

10 OVERDOSAGE
In clinical studies, single doses of finasteride up to 400 mg and multiple doses of finasteride up to 80 mg/day for three months did not result in adverse reactions. Until further experience is obtained, no specific treatment for an overdose with finasteride can be recommended.

Significant lethality was observed in male and female mice at single oral doses of 1500 mg/m^2 (500 mg/kg) and in female and male rats at single oral doses of 2360 mg/m^2 (400 mg/kg) and 5900 mg/m^2 (1000 mg/kg), respectively.

11 DESCRIPTION
PROPECIA (finasteride) tablets contain finasteride as the active ingredient. Finasteride, a synthetic 4-azasteroid compound, is a specific inhibitor of steroid Type II 5α-reductase, an intracellular enzyme that converts the androgen testosterone into 5α-dihydrotestosterone (DHT).

The chemical name of finasteride is *N-tert*-Butyl-3-oxo-4-aza-5α-androst-1-ene-17β-carboxamide. The empirical formula of finasteride is $C_{23}H_{36}N_2O_2$ and its molecular weight is 372.55. Its structural formula is:



Finasteride is a white crystalline powder with a melting point near 250°C. It is freely soluble in chloroform and in lower alcohol solvents but is practically insoluble in water.

PROPECIA (finasteride) tablets are film-coated tablets for oral administration. Each tablet contains 1 mg of finasteride and the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, hydroxypropyl methylcellulose, hydroxypropyl cellulose, titanium dioxide, magnesium stearate, talc, docusate sodium, yellow ferric oxide, and red ferric oxide.

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Finasteride is a competitive and specific inhibitor of Type II 5α-reductase, an intracellular enzyme that converts the androgen testosterone into DHT. Two distinct isozymes are found in mice, rats, monkeys, and humans: Type I and II. Each of these isozymes is differentially expressed in tissues and developmental stages. In humans, Type I 5α-reductase is predominant in the sebaceous glands of most regions of skin, including scalp, and liver. Type I 5α-reductase is responsible for approximately one-third of circulating DHT. The Type II 5α-reductase isozyme is primarily found in prostate, seminal vesicles, epididymides, and hair follicles as well as liver, and is responsible for two-thirds of circulating DHT.

In humans, the mechanism of action of finasteride is based on its preferential inhibition of the Type II isozyme. Using native tissues (scalp and prostate), *in vitro* binding studies examining the potential of finasteride to inhibit either isozyme revealed a 100-fold selectivity for the human Type II 5α-reductase over Type I isozyme (IC_{50}=500 and 4.2 nM for Type I and II, respectively). For both isozymes, the inhibition by finasteride is accompanied by reduction of the inhibitor to dihydrofinasteride and adduct formation with NADP+. The turnover for the enzyme complex is slow ($t_{1/2}$ approximately 30 days for the Type II enzyme complex and 14 days for the Type I complex). Inhibition of Type II 5α-reductase blocks the peripheral conversion of testosterone to DHT, resulting in significant decreases in serum and tissue DHT concentrations.

In men with male pattern hair loss (androgenetic alopecia), the balding scalp contains miniaturized hair follicles and increased amounts of DHT compared with hairy scalp. Administration of finasteride decreases scalp and serum DHT concentrations in these men. The relative contributions of these reductions to the treatment effect of finasteride have not been defined. By this mechanism, finasteride appears to interrupt a key factor in the development of androgenetic alopecia in those patients genetically predisposed.

12.2 Pharmacodynamics

Finasteride produces a rapid reduction in serum DHT concentration, reaching 65% suppression within 24 hours of oral dosing with a 1-mg tablet. Mean circulating levels of testosterone and estradiol were increased by approximately 15% as compared to baseline, but these remained within the physiologic range.

Finasteride has no affinity for the androgen receptor and has no androgenic, antiandrogenic, estrogenic, antiestrogenic, or progestational effects. In studies with finasteride, no clinically meaningful changes in luteinizing hormone (LH), follicle-stimulating hormone (FSH) or prolactin were detected. In healthy volunteers, treatment with finasteride did not alter the response of LH and FSH to gonadotropin-releasing hormone indicating that the hypothalamic-pituitary-testicular axis was not affected. Finasteride had no effect on circulating levels of cortisol, thyroid-stimulating hormone, or thyroxine, nor did it affect the plasma lipid profile (e.g., total cholesterol, low-density lipoproteins, high-density lipoproteins and triglycerides) or bone mineral density.

12.3 Pharmacokinetics

Absorption

In a study in 15 healthy young male subjects, the mean bioavailability of finasteride 1-mg tablets was 65% (range 26-170%), based on the ratio of area under the curve (AUC) relative to an intravenous (IV) reference dose. At steady state following dosing with 1 mg/day (n=12), maximum finasteride plasma concentration averaged 9.2 ng/mL (range, 4.9-13.7 ng/mL) and was reached 1 to 2 hours postdose; $AUC_{(0\text{-}24\ hr)}$ was 53 ng•hr/mL (range, 20-154 ng•hr/mL). Bioavailability of finasteride was not affected by food.

Distribution

Mean steady-state volume of distribution was 76 liters (range, 44-96 liters; n=15). Approximately 90% of circulating finasteride is bound to plasma proteins. There is a slow accumulation phase for finasteride after multiple dosing.

Finasteride has been found to cross the blood-brain barrier.

Semen levels have been measured in 35 men taking finasteride 1 mg/day for 6 weeks. In 60% (21 of 35) of the samples, finasteride levels were undetectable (<0.2 ng/mL). The mean finasteride level was 0.26 ng/mL and the highest level measured was 1.52 ng/mL. Using the highest semen level measured and assuming 100% absorption from a 5-mL ejaculate per day, human exposure through vaginal absorption would be up to 7.6 ng per day, which is 650-fold less than the dose of finasteride (5 µg) that had no effect on circulating DHT levels in men. [*See Use in Specific Populations (8.1).*]

Metabolism

Finasteride is extensively metabolized in the liver, primarily via the cytochrome P450 3A4 enzyme subfamily. Two metabolites, the t-butyl side chain monohydroxylated and monocarboxylic acid metabolites, have been identified that possess no more than 20% of the 5α-reductase inhibitory activity of finasteride.

Excretion
Following intravenous infusion in healthy young subjects (n=15), mean plasma clearance of finasteride was 165 mL/min (range, 70-279 mL/min). Mean terminal half-life in plasma was 4.5 hours (range, 3.3-13.4 hours; n=12). Following an oral dose of ^{14}C-finasteride in man (n=6), a mean of 39% (range, 32-46%) of the dose was excreted in the urine in the form of metabolites; 57% (range, 51-64%) was excreted in the feces.

Mean terminal half-life is approximately 5-6 hours in men 18-60 years of age and 8 hours in men more than 70 years of age.

TABLE 3
Mean (SD) Pharmacokinetic Parameters in Healthy Men (ages 18-26)

	Mean (± SD) n=15
Bioavailability	65% (26-170%)*
Clearance (mL/min)	165 (55)
Volume of Distribution (L)	76 (14)

*Range

TABLE 4
Mean (SD) Noncompartmental Pharmacokinetic Parameters After Multiple Doses of 1 mg/day in Healthy Men (ages 19-42)

	Mean (± SD) (n=12)
AUC (ng•hr/mL)	53 (33.8)
Peak Concentration (ng/mL)	9.2 (2.6)
Time to Peak (hours)	1.3 (0.5)
Half-Life (hours)*	4.5 (1.6)

*First-dose values; all other parameters are last-dose values

Renal Impairment
No dosage adjustment is necessary in patients with renal impairment. In patients with chronic renal impairment, with creatinine clearances ranging from 9.0 to 55 mL/min, AUC, maximum plasma concentration, half-life, and protein binding after a single dose of ^{14}C-finasteride were similar to those obtained in healthy volunteers. Urinary excretion of metabolites was decreased in patients with renal impairment. This decrease was associated with an increase in fecal excretion of metabolites. Plasma concentrations of metabolites were significantly higher in patients with renal impairment (based on a 60% increase in total radioactivity AUC). However, finasteride has been tolerated in men with normal renal function receiving up to 80 mg/day for 12 weeks where exposure of these patients to metabolites would presumably be much greater.

Hepatic Impairment
The effect of hepatic impairment on finasteride pharmacokinetics has not been studied. Caution should be used in the administration of PROPECIA in patients with liver function abnormalities, as finasteride is metabolized extensively in the liver.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No evidence of a tumorigenic effect was observed in a 24-month study in Sprague-Dawley rats receiving doses of finasteride up to 160 mg/kg/day in males and 320 mg/kg/day in females. These doses produced respective systemic exposure in rats of 888 and 2192 times those observed in man receiving the recommended human dose of 1 mg/day. All exposure calculations were based on calculated $AUC_{(0\text{-}24\ hr)}$ for animals and mean $AUC_{(0\text{-}24\ hr)}$ for man (0.05 µg•hr/mL).

In a 19-month carcinogenicity study in CD-1 mice, a statistically significant ($p \leq 0.05$) increase in the incidence of testicular Leydig cell adenomas was observed at 1824 times the human exposure (250 mg/kg/day). In mice at 184

times the human exposure, estimated (25 mg/kg/day) and in rats at 312 times the human exposure (≥40 mg/kg/day) an increase in the incidence of Leydig cell hyperplasia was observed. A positive correlation between the proliferative changes in the Leydig cells and an increase in serum LH levels (2- to 3-fold above control) has been demonstrated in both rodent species treated with high doses of finasteride. No drug-related Leydig cell changes were seen in either rats or dogs treated with finasteride for 1 year at 240 and 2800 times (20 mg/kg/day and 45 mg/kg/day, respectively), or in mice treated for 19 months at 18.4 times the human exposure, estimated (2.5 mg/kg/day).

No evidence of mutagenicity was observed in an *in vitro* bacterial mutagenesis assay, a mammalian cell mutagenesis assay, or in an *in vitro* alkaline elution assay. In an *in vitro* chromosome aberration assay, using Chinese hamster ovary cells, there was a slight increase in chromosome aberrations. In an *in vivo* chromosome aberration assay in mice, no treatment-related increase in chromosome aberration was observed with finasteride at the maximum tolerated dose of 250 mg/kg/day (1824 times the human exposure) as determined in the carcinogenicity studies.

In sexually mature male rabbits treated with finasteride at 4344 times the human exposure (80 mg/kg/day) for up to 12 weeks, no effect on fertility, sperm count, or ejaculate volume was seen. In sexually mature male rats treated with 488 times the human exposure (80 mg/kg/day), there were no significant effects on fertility after 6 or 12 weeks of treatment; however, when treatment was continued for up to 24 or 30 weeks, there was an apparent decrease in fertility, fecundity, and an associated significant decrease in the weights of the seminal vesicles and prostate. All these effects were reversible within 6 weeks of discontinuation of treatment. No drug-related effect on testes or on mating performance has been seen in rats or rabbits. This decrease in fertility in finasteride-treated rats is secondary to its effect on accessory sex organs (prostate and seminal vesicles) resulting in failure to form a seminal plug. The seminal plug is essential for normal fertility in rats but is not relevant in man.

14 CLINICAL STUDIES

14.1 Studies in Men

The efficacy of PROPECIA was demonstrated in men (88% Caucasian) with mild to moderate androgenetic alopecia (male pattern hair loss) between 18 and 41 years of age. In order to prevent seborrheic dermatitis which might confound the assessment of hair growth in these studies, all men, whether treated with finasteride or placebo, were instructed to use a specified, medicated, tar-based shampoo (Neutrogena T/Gel®* Shampoo) during the first 2 years of the studies.

There were three double-blind, randomized, placebo-controlled studies of 12-month duration. The two primary endpoints were hair count and patient self-assessment; the two secondary endpoints were investigator assessment and ratings of photographs. In addition, information was collected regarding sexual function (based on a self-administered questionnaire) and non-scalp body hair growth. The three studies were conducted in 1879 men with mild to moderate, but not complete, hair loss. Two of the studies enrolled men with predominantly mild to moderate vertex hair loss (n=1553). The third enrolled men having mild to moderate hair loss in the anterior mid-scalp area with or without vertex balding (n=326).

Studies in Men with Vertex Baldness

Of the men who completed the first 12 months of the two vertex baldness trials, 1215 elected to continue in double-blind, placebo-controlled, 12-month extension studies. There were 547 men receiving PROPECIA for both the initial study and first extension periods (up to 2 years of treatment) and 60 men receiving placebo for the same periods. The extension studies were continued for 3 additional years, with 323 men on PROPECIA and 23 on placebo entering the fifth year of the study.

In order to evaluate the effect of discontinuation of therapy, there were 65 men who received PROPECIA for the initial 12 months followed by placebo in the first 12-month extension period. Some of these men continued in additional extension studies and were switched back to treatment with PROPECIA, with 32 men entering the fifth year of the study. Lastly, there were 543 men who received placebo for the initial 12 months followed by PROPECIA in the first 12-month extension period. Some of these men continued in additional extension studies receiving PROPECIA, with 290 men entering the fifth year of the study (see Figure 1 below).

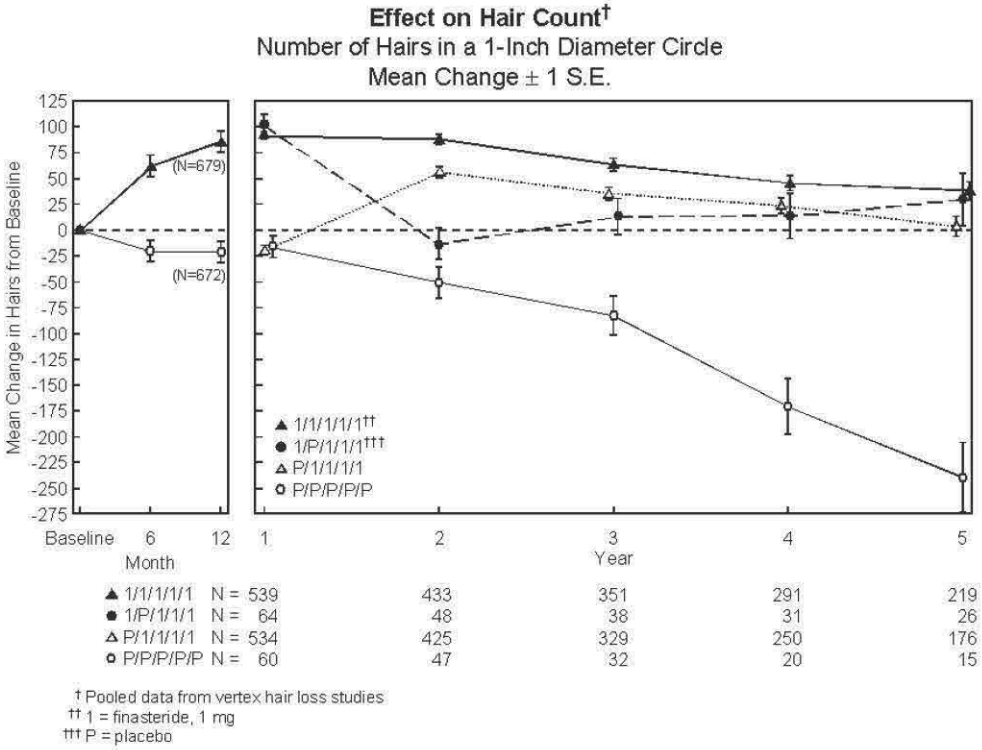
*Registered trademark of Johnson & Johnson

Hair counts were assessed by photographic enlargements of a representative area of active hair loss. In these two studies in men with vertex baldness, significant increases in hair count were demonstrated at 6 and 12 months in men treated with PROPECIA, while significant hair loss from baseline was demonstrated in those treated with placebo. At 12 months there was a 107-hair difference from placebo ($p<0.001$, PROPECIA [n=679] vs placebo [n=672]) within a 1-inch diameter circle (5.1 cm^2). Hair count was maintained in those men taking PROPECIA for up to 2 years, resulting in a 138-hair difference between treatment groups ($p<0.001$, PROPECIA [n=433] vs placebo [n=47]) within the same area. In men treated with PROPECIA, the maximum improvement in hair count compared to baseline was achieved during the first 2 years. Although the initial improvement was followed by a slow decline, hair count was maintained above baseline throughout the 5 years of the studies. Furthermore, because the decline in the placebo group was more rapid, the difference between treatment groups also continued to increase throughout the studies, resulting in a 277-hair difference ($p<0.001$, PROPECIA [n=219] vs placebo [n=15]) at 5 years (see Figure 1 below).

Patients who switched from placebo to PROPECIA (n=425) had a decrease in hair count at the end of the initial 12-month placebo period, followed by an increase in hair count after 1 year of treatment with PROPECIA. This increase in hair count was less (56 hairs above original baseline) than the increase (91 hairs above original baseline) observed after 1 year of treatment in men initially randomized to PROPECIA. Although the increase in hair count, relative to when therapy was initiated, was comparable between these two groups, a higher absolute hair count was achieved in patients who were started on treatment with PROPECIA in the initial study. This advantage was maintained through the remaining 3 years of the studies. A change of treatment from PROPECIA to placebo (n=48) at the end of the initial 12 months resulted in reversal of the increase in hair count 12 months later, at 24 months (see Figure 1 below).

At 12 months, 58% of men in the placebo group had further hair loss (defined as any decrease in hair count from baseline), compared with 14% of men treated with PROPECIA. In men treated for up to 2 years, 72% of men in the placebo group demonstrated hair loss, compared with 17% of men treated with PROPECIA. At 5 years, 100% of men in the placebo group demonstrated hair loss, compared with 35% of men treated with PROPECIA.

Figure 1



† Pooled data from vertex hair loss studies
†† 1 = finasteride, 1 mg
††† P = placebo

Patient self-assessment was obtained at each clinic visit from a self-administered questionnaire, which included questions on their perception of hair growth, hair loss, and appearance. This self-assessment demonstrated an increase in amount of hair, a decrease in hair loss, and improvement in appearance in men treated with PROPECIA. Overall improvement compared with placebo was seen as early as 3 months ($p<0.05$), with improvement maintained over 5 years.

Investigator assessment was based on a 7-point scale evaluating increases or decreases in scalp hair at each patient visit. This assessment showed significantly greater increases in hair growth in men treated with PROPECIA compared with placebo as early as 3 months ($p<0.001$). At 12 months, the investigators rated 65% of men treated with PROPECIA as having increased hair growth compared with 37% in the placebo group. At 2 years, the investigators rated 80% of men treated with PROPECIA as having increased hair growth compared with 47% of men treated with placebo. At 5 years, the investigators rated 77% of men treated with PROPECIA as having increased hair growth, compared with 15% of men treated with placebo.

An independent panel rated standardized photographs of the head in a blinded fashion based on increases or decreases in scalp hair using the same 7-point scale as the investigator assessment. At 12 months, 48% of men treated with PROPECIA had an increase as compared with 7% of men treated with placebo. At 2 years, an increase in hair growth was demonstrated in 66% of men treated with PROPECIA, compared with 7% of men treated with placebo. At 5 years, 48% of men treated with PROPECIA demonstrated an increase in hair growth, 42% were rated as having no change (no further visible progression of hair loss from baseline) and 10% were rated as having lost hair when compared to baseline. In comparison, 6% of men treated with placebo demonstrated an increase in hair growth, 19% were rated as having no change and 75% were rated as having lost hair when compared to baseline.

A 48-week, placebo-controlled study designed to assess by phototrichogram the effect of PROPECIA on total and actively growing (anagen) scalp hairs in vertex baldness enrolled 212 men with androgenetic alopecia. At baseline and 48 weeks, total and anagen hair counts were obtained in a 1-cm^2 target area of the scalp. Men treated with PROPECIA showed increases from baseline in total and anagen hair counts of 7 hairs and 18 hairs, respectively, whereas men treated with placebo had decreases of 10 hairs and 9 hairs, respectively. These changes in hair counts resulted in a between-group difference of 17 hairs in total hair count ($p<0.001$) and 27 hairs in anagen hair count ($p<0.001$), and an improvement in the proportion of anagen hairs from 62% at baseline to 68% for men treated with PROPECIA.

Other Results in Vertex Baldness Studies

A sexual function questionnaire was self-administered by patients participating in the two vertex baldness trials to detect more subtle changes in sexual function. At Month 12, statistically significant differences in favor of placebo were found in 3 of 4 domains (sexual interest, erections, and perception of sexual problems). However, no significant difference was seen in the question on overall satisfaction with sex life.

In one of the two vertex baldness studies, patients were questioned on non-scalp body hair growth. PROPECIA did not appear to affect non-scalp body hair.

Study in Men with Hair Loss in the Anterior Mid-Scalp Area

A study of 12-month duration, designed to assess the efficacy of PROPECIA in men with hair loss in the anterior mid-scalp area, also demonstrated significant increases in hair count compared with placebo. Increases in hair count were accompanied by improvements in patient self-assessment, investigator assessment, and ratings based on standardized photographs. Hair counts were obtained in the anterior mid-scalp area, and did not include the area of bitemporal recession or the anterior hairline.

Summary of Clinical Studies in Men

Clinical studies were conducted in men aged 18 to 41 with mild to moderate degrees of androgenetic alopecia. All men treated with PROPECIA or placebo received a tar-based shampoo (Neutrogena T/Gel® Shampoo) during the first 2 years of the studies. Clinical improvement was seen as early as 3 months in the patients treated with PROPECIA and led to a net increase in scalp hair count and hair regrowth. In clinical studies for up to 5 years, treatment with PROPECIA slowed the further progression of hair loss observed in the placebo group. In general, the difference between treatment groups continued to increase throughout the 5 years of the studies.

Ethnic Analysis of Clinical Data from Men
In a combined analysis of the two studies on vertex baldness, mean hair count changes from baseline were 91 vs -19 hairs (PROPECIA vs placebo) among Caucasians (n=1185), 49 vs -27 hairs among Blacks (n=84), 53 vs -38 hairs among Asians (n=17), 67 vs 5 hairs among Hispanics (n=45) and 67 vs -15 hairs among other ethnic groups (n=20). Patient self-assessment showed improvement across racial groups with PROPECIA treatment, except for satisfaction of the frontal hairline and vertex in Black men, who were satisfied overall.

14.2 Study in Women
In a study involving 137 postmenopausal women with androgenetic alopecia who were treated with PROPECIA (n=67) or placebo (n=70) for 12 months, effectiveness could not be demonstrated. There was no improvement in hair counts, patient self-assessment, investigator assessment, or ratings of standardized photographs in the women treated with PROPECIA when compared with the placebo group [*see Indications and Usage (1.1)*].

16 HOW SUPPLIED/STORAGE AND HANDLING
No. 6642 — PROPECIA tablets, 1 mg, are tan, octagonal, film-coated convex tablets with "stylized P" logo on one side and PROPECIA on the other. They are supplied as follows:

NDC 0006-0071-31 bottles of 30 (with desiccant)
NDC 0006-0071-54 PROPAK® bottles of 90 (with desiccant).

Storage and Handling
Store at room temperature, 15-30°C (59-86°F). Keep container closed and protect from moisture.

Women should not handle crushed or broken PROPECIA tablets when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets are not broken or crushed [*see Warnings and Precautions (5.1), Use in Specific Populations (8.1) and Patient Counseling Information (17.1)*].

17 PATIENT COUNSELING INFORMATION
"See FDA-approved patient labeling (Patient Information)"

17.1 Exposure of Women — Risk to Male Fetus
Physicians should inform patients that women who are pregnant or may potentially be pregnant should not handle crushed or broken PROPECIA tablets because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed. If a woman who is pregnant or may potentially be pregnant comes in contact with crushed or broken PROPECIA tablets, the contact area should be washed immediately with soap and water [*see Contraindications (4), Warnings and Precautions (5.1), Use in Specific Populations (8.1) and How Supplied/Storage and Handling (16)*].

17.2 Increased Risk of High-Grade Prostate Cancer
Patients should be informed that there was an increase in high-grade prostate cancer in men treated with 5α-reductase inhibitors indicated for BPH treatment, compared to those treated with placebo in studies looking at the use of these drugs to prevent prostate cancer [*see Warnings and Precautions (5.3) and Adverse Reactions (6.1)*].

17.3 Additional Instructions
Physicians should instruct their patients to promptly report any changes in their breasts such as lumps, pain or nipple discharge. Breast changes including breast enlargement, tenderness and neoplasm have been reported [*see Adverse Reactions (6.1)*].

Physicians should instruct their patients to read the patient package insert before starting therapy with PROPECIA and to read it again each time the prescription is renewed so that they are aware of current information for patients regarding PROPECIA.

PROPECIA® (finasteride) Tablets

Dist. by: Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC., Whitehouse Station, NJ 08889, USA

US Patent Nos.: 5,547,957; 5,571,817

Revised: 04/2012

Patient Information
PROPECIA (Pro-pee-sha)
(finasteride)
Tablets

PROPECIA® is for use by **MEN ONLY** and should **NOT** be used by women or children.

Read this Patient Information before you start taking PROPECIAand each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is PROPECIA?

PROPECIA is a prescription medicine used for the treatment of male pattern hair loss (androgenetic alopecia).

It is not known if PROPECIA works for a receding hairline on either side of and above your forehead (temporal area).

PROPECIA is not for use by women and children.

Who should not take PROPECIA?

Do not take PROPECIA if you:

- are pregnant or may become pregnant. PROPECIA may harm your unborn baby.
    - PROPECIA tablets are coated and will prevent contact with the medicine during handling, as long as the tablets are not broken or crushed. Females who are pregnant or who may become pregnant should not come in contact with broken or crushed PROPECIA tablets. If a pregnant woman comes in contact with crushed or broken PROPECIA tablets, wash the contact area right away with soap and water. If a woman who is pregnant comes into contact with the active ingredient in PROPECIA, a healthcare provider should be consulted.
    - If a woman who is pregnant with a male baby swallows or comes in contact with the medicine in PROPECIA, the male baby may be born with sex organs that are not normal.
- are allergic to any of the ingredients in PROPECIA. See the end of this leaflet for a complete list of ingredients in PROPECIA.

What should I tell my healthcare provider before taking PROPECIA?

Before taking PROPECIA, tell your healthcare provider if you:

- have any other medical conditions, including problems with your prostate or liver

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take PROPECIA?

- Take PROPECIA exactly as your healthcare provider tells you to take it.
- You may take PROPECIA with or without food.
- If you forget to take PROPECIA do not take an extra tablet. Just take the next tablet as usual.

PROPECIA will not work faster or better if you take it more than once a day.

What are the possible side effects of PROPECIA?

- **decrease in your blood Prostate Specific Antigen (PSA) levels.** PROPECIA can affect a blood test called PSA (Prostate Specific Antigen) for the screening of prostate cancer. If you have a PSA test done you should tell your healthcare provider that you are taking PROPECIA because PROPECIA decreases PSA levels. Changes in PSA levels will need to be evaluated by your healthcare provider. Any increase in follow-up PSA levels from their lowest point may signal the presence of prostate cancer and should be evaluated, even if the test results are still within the normal range for men not taking PROPECIA. You should also tell your healthcare provider if you have not been taking PROPECIA as prescribed because this may affect the PSA test results. For more information, talk to your healthcare provider.
- There may be an increased risk of a more serious form of prostate cancer in men taking finasteride at 5 times the dose of PROPECIA.

The most common side effects of PROPECIA include:

- decrease in sex drive

- trouble getting or keeping an erection
- a decrease in the amount of semen

The following have been reported in general use with PROPECIA:

- breast tenderness and enlargement. Tell your healthcare provider about any changes in your breasts such as lumps, pain or nipple discharge.
- depression;
- decrease in sex drive that continued after stopping the medication;
- allergic reactions including rash, itching, hives and swelling of the lips and face;
- problems with ejaculation that continued after stopping medication;
- testicular pain;
- difficulty in achieving an erection that continued after stopping the medication;
- male infertility and/or poor quality of semen.
- in rare cases, male breast cancer.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of PROPECIA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PROPECIA?

- Store PROPECIA at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep PROPECIA in a closed container and keep PROPECIA tablets dry (protect from moisture).

Keep PROPECIA and all medicines out of the reach of children.

General information about the safe and effective use of PROPECIA.

Medicines are sometimes prescribed for purposes other than those listed in this Patient Information leaflet. Do not use PROPECIA for a condition for which it was not prescribed. Do not give PROPECIA to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about PROPECIA. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about PROPECIA

that is written for health professionals. For more information, **call 1-888-637-2522.**

What are the ingredients in PROPECIA?

Active ingredient: finasteride.

Inactive ingredients: lactose monohydrate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, hydroxypropyl methylcellulose, hydroxypropyl cellulose, titanium dioxide, magnesium stearate, talc, docusate sodium, yellow ferric oxide, and red ferric oxide.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Dist. by: Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC., Whitehouse Station, NJ 08889, USA

US Patent Nos.: 5,547,957; 5,571,817

Revised: 04/2012

EXHIBIT B

DOCUMENTS AND THINGS

Please produce the documents and things requested below, that are in your possession not including those items covered by the Attorney-Client or Work Product Privileges. If you withhold a document or information otherwise discoverable by claiming that it is privileged or otherwise protected, you shall make any such claim expressly and describe the nature of the information or document not produced or disclosed in a manner that enables other parties to assess the applicability of the privilege or protection, in accordance with the requirements of Fed. R. Civ. P. 26(b)(5).

1. For each health care practitioner who has examined you, treated you, or consulted with other health care practitioners regarding your medical or dental condition within ten (10) years of your first use of Propecia and/or Proscar to the present, produce an executed copy of the release form attached to this Plaintiff's Profile Form as Ex. A, authorizing Merck to obtain medical records, including all radiological or imaging records from each health care practitioner and/or in your possession.

2. For each hospital, clinic or any other facility at which you have been treated for any medical condition within ten (10) years of your first use of Propecia and/or Proscar to the present, produce an executed copy of the release form attached as Ex. A, authorizing Merck to obtain medical records from each such hospital, clinic or any other facility.

3. For any health care practitioner that examined you, treated you, or consulted with other health care practitioners regarding your medical condition at or in affiliation with a Veteran's Administration facility, please produce an executed copy of the release form attached as Ex. A, authorizing Merck to obtain medical records from each health care practitioner.

4. For any psychologist, psychiatrist or other mental health care practitioner that treated you within seven (7) years of your first use of Propecia and/or Proscar, please produce an executed copy of the release form attached as Ex. B, authorizing Merck to obtain mental health records from each mental health care practitioner.

5. If you have been a claimant in a worker's compensation, Social Security or other disability proceeding, please produce an executed copy of the release form attached as Ex. C, authorizing Merck to obtain all documents discussing, describing or memorializing your requests for Social Security, disability insurance, or workers' compensation benefits.

6. If you are making a wage loss or loss of earning capacity claim, for each of your employers identified, please produce two executed copies of the release forms attached as Ex. D, permitting Merck to obtain your employment records, including W-2 forms and/or 1099 forms from three years prior to the date of the claimed wage loss or loss of earning capacity.

7. If you served in the military, please produce an executed copy of Standard Form 180

attached as Ex. E, permitting Merck to obtain your military personnel, service, and health records.

8. For each health insurance company or other organization that has insured you from ten years (10) years prior to your first use of Propecia and/or Proscar to the present, produce an executed copy of the authorization, attached as Ex. A, authorizing Merck to obtain all insurance records from each such company.

9. Please produce any documents, in your possession, constituting, concerning or relating to product use instructions, product warnings, package inserts, handouts or other materials distributed with or provided to you in connection with your use of Propecia and/or Proscar.

10. Please produce any documents, in your possession, containing copies of advertisements, written or Internet materials or promotions for Propecia and/or Proscar, not including those items covered by the Attorney-Client or Work Product Privileges.

11. Please produce any documents, in your possession of copies of all printouts from websites you visited regarding Propecia and/or Proscar, regarding your injuries and/or this lawsuit, not including those items covered by the Attorney-Client or Work Product Privileges.

12. Please produce any documents including copies of transcripts, in your possession of Internet chat room discussions in which you participated regarding Propecia and/or Proscar, your injuries and/or this lawsuit, not including those items covered by the Attorney-Client or Work Product Privileges.

13. Please produce any documents including email, in your possession relating to Propecia and/or Proscar, your injuries and/or this lawsuit, not including those items covered by the Attorney-Client or Work Product Privileges.

14. Please produce any documents, in your possession relating to Propecia and/or Proscar or any alleged health risks or hazards related to these drugs in your possession at or before the time of your claimed injury.

15. Please produce any documents, in your possession that you (and not your lawyer) obtained directly or indirectly from Merck related to Proscar or Propecia.

16. Please produce any documents, in your possession of all diaries, calendars or any other writings or recordings made by you, or by any other person, describing, discussing, explaining or referring to the injuries, damages, or causes of action alleged by you in the Complaint and/or referring to the underlying illness or disease for which you received Propecia and/or Proscar, not including those items covered by the Attorney-Client or Work Product Privileges.

17. Please produce any documents, in your possession that you (and not your attorneys)

obtained from any source related to Propecia and/or Proscar or to the alleged effects of such medications, not including those items covered by the Attorney-Client or work Product Privileges.

18. If you are claiming any loss from medical expenses, please produce any documents copies of all bills from any physician, hospital pharmacy or other health care provider that are in your possession.

19. If this claim is a claim alleging Propecia and/or Proscar caused the wrongful death of the Decedent, Decedent's death certificate (if applicable).

ButlerSnow 15049210v1

LIMITED AUTHORIZATION TO DISCLOSE AND HEALTH INFORMATION
(Pursuant to the Health Insurance Portability and Accountability Act "HIPAA" of 4/14/03)

TO:_____

Patient Name: _____
DOB: _____
SSN: _____

I, _____, hereby authorize you to release and furnish to: **Litigation Management, Inc, 6600 Parkland Blvd, Mayfield Hts., OH 44124 as an agent for Butler, Snow, O'Mara, Stevens & Cannada, PLLC, 1020 Highland Colony Parkway, Suite 1400, Ridgeland, MS 39157, COPIES ONLY** of the following information:

* All medical records, including inpatient, outpatient, and emergency room treatment, all clinical charts, reports, documents, correspondence, test results, statements, questionnaires/histories, office and doctor's handwritten notes, and records received by other physicians. Said medical records shall include all information regarding AIDS and HIV status.
* All **reports** of autopsy, laboratory, histology, cytology, pathology, radiology, CT Scan, MRI, echocardiogram and cardiac catheterization reports.
* All radiology films, mammograms, myelograms, CT scans, photographs, bone scans, pathology/cytology/histology/autopsy/immunohistochemistry specimens, cardiac catheterization videos/CDs/films/reels, and echocardiogram videos.
* All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
* All billing records including all statements, itemized bills, and insurance records.

1. To my medical provider: **this authorization is being forwarded by, or on behalf of, attorneys for the defendants. You are not authorized to discuss any aspect of the above-named person's medical history, care, treatment, diagnosis, prognosis, information revealed by or in the medical records, or any other matter bearing on his or her medical or physical condition, unless you receive and additional authorization permitting such discussion. Subject to all applicable legal objections, this restriction does not apply to discussing my medical history, care, treatment, diagnosis, prognosis, information revealed by or in the medical records, or any other matter bearing on my medical or physical condition at a deposition or trial.**

2. I understand that the information in my health record may include information relating to sexually transmitted disease, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency virus (HIV). It may also include information about behavioral or mental health services, and treatment for alcohol and drug abuse.

3. I understand that I have the right to revoke this authorization at any time. I understand that if I revoke this authorization I must do so in writing and present my written revocation to the health information management department. I understand the revocation will not apply to information that has already been released in response to this authorization. I understand the revocation will not apply to my insurance company when the law provides my insurer with the right to contest a claim under my policy. Unless otherwise revoked, this authorization will expire in one year.

4. I understand that authorizing the disclosure of this health information is voluntary. I can refuse to sign this authorization. I need not sign his form in order to assure treatment. I understand I may inspect or copy the information to be used or disclosed as provided in CFR 164.524. I understand that any disclosure of information carries with it the potential for an unauthorized re-disclosure and the information may not be protected by federal confidentiality rules. If I have questions about disclosure of my health information, I can contact the releaser indicate above.

5. A notarized signature is not required. CFR 164.508. A copy of this authorization may be used in place of an original.

Print Name: _____(plaintiff/representative)
Signature: _____ DATE: _____

OMB Number: 2900-0200
Estimated Burden: 2 minutes

Department of Veterans Affairs

REQUEST FOR AND AUTHORIZATION TO RELEASE MEDICAL RECORDS OR HEALTH INFORMATION

Privacy Act and Paperwork Reduction Act Information: The execution of this form does not authorize the release of information other than that specifically described below. The information requested on this form is solicited under Title 38, U.S.C. The form authorizes release of information in accordance with the Health Insurance Portability and Accountability Act, 45 CFR Parts 160 and 164, 5 U.S.C. 552a, and 38 U.S.C. 5701 and 7332 that you specify. Your disclosure of the information requested on this form is voluntary. However, if the information including Social Security Number (SSN) (the SSN will be used to locate records for release) is not furnished completely and accurately, Department of Veterans Affairs will be unable to comply with the request. The Veterans Health Administration may not condition treatment, payment, enrollment or eligibility on signing the authorization. VA may disclose the information that you put on the form as permitted by law. VA may make a "routine use" disclosure of the information as outlined in the Privacy Act systems of records notices identified as 24VA19 "Patient Medical Record - VA" and in accordance with the VHA Notice of Privacy Practices. You do not have to provide the information to VA, but if you don't, VA will be unable to process your request and serve your medical needs. Failure to furnish the information will not have any affect on any other benefits to which you may be entitled. If you provide VA your Social Security Number, VA will use it to administer your VA benefits. VA may also use this information to identify veterans and persons claiming or receiving VA benefits and their records, and for other purposes authorized or required by law. The Paperwork Reduction Act of 1995 requires us to notify you that this information collection is in accordance with the clearance requirements of section 3507 of the Paperwork Reduction Act of 1995. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a valid OMB number. We anticipate that the time expended by all individuals who must complete this form will average 2 minutes. This includes the time it will take to read instructions, gather the necessary facts and fill out the form.

ENTER BELOW THE PATIENT'S NAME AND SOCIAL SECURITY NUMBER IF THE PATIENT DATA CARD IMPRINT IS NOT USED.

TO: DEPARTMENT OF VETERANS AFFAIRS (Print or type name and address of health care facility)	PATIENT NAME (Last, First, Middle Initial) SOCIAL SECURITY NUMBER

NAME AND ADDRESS OF ORGANIZATION, INDIVIDUAL OR TITLE OF INDIVIDUAL TO WHOM INFORMATION IS TO BE RELEASED

VETERAN'S REQUEST: I request and authorize Department of Veterans Affairs to release the information specified below to the organization, or individual named on this request. I understand that the information to be released includes information regarding the following condition(s):

☐ DRUG ABUSE ☐ ALCOHOLISM OR ALCOHOL ABUSE ☐ TESTING FOR OR INFECTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV) ☐ SICKLE CELL ANEMIA

INFORMATION REQUESTED (Check applicable box(es) and state the extent or nature of the information to be disclosed, giving the dates or approximate dates covered by each)

☐ COPY OF HOSPITAL SUMMARY ☐ COPY OF OUTPATIENT TREATMENT NOTE(S) ☐ OTHER (Specify)

PURPOSE(S) OR NEED FOR WHICH THE INFORMATION IS TO BE USED BY INDIVIDUAL TO WHOM INFORMATION IS TO BE RELEASED

NOTE: ADDITIONAL ITEMS OF INFORMATION DESIRED MAY BE LISTED ON THE BACK OF THIS FORM

AUTHORIZATION: I certify that this request has been made freely, voluntarily and without coercion and that the information given above is accurate and complete to the best of my knowledge. I understand that I will receive a copy of this form after I sign it. I may revoke this authorization, in writing, at any time except to the extent that action has already been taken to comply with it. Written revocation is effective upon receipt by the Release of Information Unit at the facility housing the records. Redisclosure of my medical records by those receiving the above authorized information may be accomplished without my further written authorization and may no longer be protected. Without my express revocation, the authorization will automatically expire: (1) upon satisfaction of the need for disclosure; (2) on _____ (date supplied by patient); (3) under the following condition(s):

I understand that the VA health care practitioner's opinions and statements are not official VA decisions regarding whether I will receive other VA benefits or, if I receive VA benefits, their amount. They may, however, be considered with other evidence when these decisions are made at a VA Regional Office that specializes in benefit decisions.

DATE	SIGNATURE OF PATIENT OR PERSON AUTHORIZED TO SIGN FOR PATIENT (Attach authority to sign, e.g., POA)

FOR VA USE ONLY

IMPRINT PATIENT DATA CARD (or enter Name, Address, Social Security Number)	**TYPE AND EXTENT OF MATERIAL RELEASED**	
	DATE RELEASED	RELEASED BY

VA FORM MAY 2005 **10-5345** USE EXISTING STOCK OF VA FORM 10-5345, DATED NOV 2004.

AUTHORIZATION AND CONSENT
TO RELEASE PSYCHOTHERAPY NOTES

Patient Name: _____
Social Security Number: _____
Date of Birth: _____

Provider Name:_____

TO: All physicians, hospitals, clinics and institutions, pharmacists and other healthcare providers
The Veteran's Administration and all Veteran's Administration hospitals, clinics, physicians and employees

The Social Security Administration

The Internal Revenue Service

Open Records, Administrative Specialist, Department of Workers' Claims

All employers or other persons, firms, corporations, schools and other educational institutions

The undersigned individual herby authorizes each entity included in any of the above categories to furnish and disclose to **Litigation Management, Inc, 6600 Parkland Blvd, Mayfield Hts., OH 44124 as an agent for Butler, Snow, O'Mara, Stevens & Cannada, PLLC, 1020 Highland Colony Parkway, Suite 1400, Ridgeland, MS 39157,** and its authorized representatives, with true and correct copies of all "psychotherapy notes", as such term is defined by the Health Insurance Portability and Accountability Act, 45 CFR §164.501. Under HIPAA, the term "psychotherapy notes" means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint or family counseling session and that are separated from the rest of the individual's record. This authorization does not authorize ex parte communication concerning same.

- This authorization provides for the disclosure of the above-named patient's protected health information for purposes of the following litigation matter: _____ ***v. Merck & Co., Inc., et al.,*** **Case No.:** _____.
- The undersigned individual is hereby notified and acknowledges that any health care provider or health plan disclosing the above requested information may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs this authorization.
- The undersigned individual is hereby notified and acknowledges that he or she may revoke this authorization by providing written notice to either **Litigation Management, Inc, 6600 Parkland Blvd, Mayfield Hts., OH 44124** or **Butler, Snow, O'Mara, Stevens & Cannada, PLLC, Attention: Alyson B. Jones, 1020 Highland Colony Parkway, Suite 1400, Ridgeland,**

MS 39157, and/or to one or more entities listed in the above categories, except to the extent that any such entity has taken action in reliance on this authorization.

- The undersigned is hereby notified and acknowledges that he or she is aware of the potential that protected health information disclosed and furnished to the recipient pursuant to this authorization is subject to redisclosure by the recipient for the purposes of this litigation in a manner that will not be protected by the Standards for the Privacy of Individually Identifiable Health Information contained in the HIPAA regulations (45 CFR §§164.500-164.534).

- The undersigned is hereby notified that he/she is aware that any and all protected health information disclosed and furnished to Butler, Snow, O'Mara, Stevens & Cannada, PLLC pursuant to this authorization will be shared with any and all co-defendants in the matter of _____ ***v. Merck & Co., Inc., et al.,*** **Case No.:** _____. and is subject to redisclosure by the recipient for the purposes of this litigation in a manner that will not be protected by the Standards for the Privacy of Individually Identifiable Health Information contained in the HIPAA regulations (45 CFR §§164.500-164.534).

- A photocopy of this authorization shall be considered as effective and valid as the original, and this authorization will remain in effect until the later of: (i) the date of settlement or final disposition of _____ ***v. Merck & Co., Inc., et al.,*** **Case No.:** _____ *or* **(ii) five (5) years after the date of signature of the undersigned below**.

I have carefully read and understand the above and do hereby expressly and voluntarily authorize the disclosure of all of my above information to Litigation Management, Inc, 6600 Parkland Blvd, Mayfield Hts., OH 44124 as an agent for Butler, Snow, O'Mara, Stevens & Cannada, PLLC, 1020 Highland Colony Parkway, Suite 1400, Ridgeland, MS 39157, and its authorized representatives, by any entities included in the categories listed above.

Date: _____

_____
Signature of Individual or Individual's Representative

Individual's Name and Address:

_____
Printed Name of Individual's Representative (If applicable)

_____

_____
Relationship of Representative to Individual (If applicable)

_____

_____

_____

_____
Description of Representative's authority to act for Individual (If applicable)

This authorization is designed to be in compliance with the Health Insurance Portability and Accountability Act, and the regulations promulgated thereunder, 45 CFR Parts 160 and 164 (collectively, "HIPAA").

Social Security Administration
Consent for Release of Information

Form Approved
OMB No. 0960-0566

Instructions for Using this Form

Complete this form only if you want us to give information or records about you, a minor, or a legally incompetent adult, to an individual or group (for example, a doctor or an insurance company). If you are the natural or adoptive parent or legal guardian, acting on behalf of a minor, you may complete this form to release only the minor's non-medical records. If you are requesting information for a purpose not directly related to the administration of any program under the Social Security Act, a fee may be charged.

NOTE: Do not use this form to:

- Request us to release the medical records of a minor. Instead, contact your local office by calling 1-800-772-1213 (TTY-1-800-325-0778), or
- Request information about your earnings or employment history. Instead, complete form SSA-7050-F4 at any Social Security office or online at www.ssa.gov/online/ssa-7050.pdf.

How to Complete this Form

We will not honor this form unless all required fields are completed. An asterisk (*) indicates a required field. Also, we will not honor blanket requests for "all records" or the "entire file." You must specify the information you are requesting and you must sign and date this form.

- Fill in your name, date of birth, and social security number or the name, date of birth, and social security number of the person to whom the information applies.
- Fill in the name and address of the individual (or organization) to whom you want us to release your information.
- Indicate the reason you are requesting us to disclose the information.
- Check the box(es) next to the type(s) of information you want us to release including the date ranges, if applicable.
- You, the parent or legal guardian acting on behalf of a minor, or the legal guardian of a legally incompetent adult, must sign and date this form and provide a daytime phone number where you can be reached.
- If you are not the person whose information is requested, state your relationship to that person. We may require proof of relationship.

PRIVACY ACT STATEMENT

Section 205(a) of the Social Security Act, as amended, authorizes us to collect the information requested on this form. The information you provide will be used to respond to your request for SSA records information or process your request when we release your records to a third party. You do not have to provide the requested information. Your response is voluntary; however, we cannot honor your request to release information or records about you to another person or organization without your consent.

We rarely use the information provided on this form for any purpose other than to respond to requests for SSA records information. However, in accordance with 5 U.S.C. § 552a(b) of the Privacy Act, we may disclose the information provided on this form in accordance with approved routine uses, which include but are not limited to the following: 1. To enable an agency or third party to assist Social Security in establishing rights to Social Security benefits and/or coverage; 2. To make determinations for eligibility in similar health and income maintenance programs at the Federal, State, and local level; 3. To comply with Federal laws requiring the disclosure of the information from our records; and, 4. To facilitate statistical research, audit, or investigative activities necessary to assure the integrity of SSA programs.

We may also use the information you provide when we match records by computer. Computer matching programs compare our records with those of other Federal, State, or local government agencies. Information from these matching programs can be used to establish or verify a person's eligibility for Federally-funded or administered benefit programs and for repayment of payments or delinquent debts under these programs.

Additional information regarding this form, routine uses of information, and other Social Security programs are available from our Internet website at www.socialsecurity.gov or at your local Social Security office.

PAPERWORK REDUCTION ACT STATEMENT

This information collection meets the requirements of 44 U.S.C. § 3507, as amended by section 2 of the Paperwork Reduction Act of 1995. You do not need to answer these questions unless we display a valid Office of Management and Budget control number. We estimate that it will take about 3 minutes to read the instructions, gather the facts, and answer the questions. **SEND OR BRING THE COMPLETED FORM TO YOUR LOCAL SOCIAL SECURITY OFFICE. You can find your local Social Security office through SSA's website at www.socialsecurity.gov. Offices are also listed under U.S. Government agencies in your telephone directory or you may call 1-800-772-1213 (TTY 1-800-325-0778).** *You may send comments on our time estimate above to: SSA, 6401 Security Blvd., Baltimore, MD 21235-6401.* ***Send only comments relating to our time estimate to this address, not the completed form.***

Form **SSA-3288** (07-2010) EF (07-2010) Destroy Prior Editions

Social Security Administration
Consent for Release of Information

Form Approved
OMB No. 0960-0566

*SSA will not honor this form unless all required fields have been completed (*signifies required field).*

TO: Social Security Administration

*Name _____ *Date of Birth _____ *Social Security Number _____

I authorize the Social Security Administration to release information or records about me to:

*NAME _____ *ADDRESS _____

_____ _____

_____ _____

*I want this information released because: _____
There may be a charge for releasing information.

*Please release the following information selected from the list below:
You must check at least one box. Also, SSA will not disclose records unless applicable date ranges are included.

- ☐ Social Security Number
- ☐ Current monthly Social Security benefit amount
- ☐ Current monthly Supplemental Security Income payment amount
- ☐ My benefit/payment amounts from _____ to _____
- ☐ My Medicare entitlement from _____ to _____
- ☐ Medical records from my claims folder(s) from _____ to _____
  If you want SSA to release a minor's medical records, do not use this form but instead contact your local SSA office.
- ☐ Complete medical records from my claims folder(s)
- ☐ Other record(s) from my file (e.g. applications, questionnaires, consultative examination reports, determinations, etc.) _____

I am the individual to whom the requested information/record applies, or the parent or legal guardian of a minor, or the legal guardian of a legally incompetent adult. I declare under penalty of perjury in accordance with 28 C.F.R. § 16.41(d)(2004) that I have examined all the information on this form, and on any accompanying statements or forms, and it is true and correct to the best of my knowledge. I understand that anyone who knowingly or willfully seeking or obtaining access to records about another person under false pretenses is punishable by a fine of up to $5,000. I also understand that any applicable fees must be paid by me.

*Signature: _____ *Date: _____

Relationship *(if not the individual)*: _____ *Daytime Phone: _____

Form **SSA-3288** (07-2010) EF (07-2010)

Social Security Administration

Form Approved
OMB No. 0960-0525

REQUEST FOR SOCIAL SECURITY EARNINGS INFORMATION

*Use This Form If You Need

1. Certified/Non-Certified Detailed Earnings Information

Includes periods of employment or self-employment and the names and addresses of employers.

OR

2. Certified Yearly Totals of Earnings

Includes total earnings for each year but does not include the names and addresses of employers.

DO NOT USE THIS FORM FOR:

Non-certified yearly totals of earnings

This service is free to the public.

These totals can be obtained by calling 1-800-772-1213 to receive Form SSA-7004, Request for Social Security Statement

PRIVACY ACT NOTICE: We are authorized to collect this information under section 205 of the Social Security Act, and the Federal Records Act of 1950 (64 Stat. 583). It is needed so we can identify your records and prepare the statement you request. You do not have to furnish the information, but failure to do so may prevent your request from being processed.

Paperwork Reduction Act Statement - This information collection meets the requirements of 44 U.S.C. § 3507, as amended by section 2 of the Paperwork Reduction Act of 1995. You do not need to answer these questions unless we display a valid Office of Management and Budget control number. We estimate that it will take about 11 minutes to read the instructions, gather the facts, and answer the questions. ***Send only comments relating to our time estimate above to:*** SSA, 6401 Security Blvd, Baltimore, MD 21235-6401.

INFORMATION ABOUT YOUR REQUEST

- **How Do I Get This Information?**

  You need to complete the attached form to tell us what information you want.

- **Can I Get This Information For Someone Else?**

  Yes, if you have their written permission. For more information, see page 3.

- **Who Can Sign On Behalf Of The Individual?**

  The parent of a minor child, or the legal guardian of an individual who has been declared legally incompetent, may sign if he/she is acting on behalf of the individual.

- **Is There A Fee For This Information?**

  1. Certified/Non-Certified Detailed Earnings Information

  Yes, we usually charge a fee for detailed information. In most cases, this information is used for purposes NOT directly related to Social Security such as for a private pension plan or personal injury suit. The fee chart on page 3 gives the amount of the charge.

  Sometimes, there is no charge for detailed information. If you have reason to believe your earnings are not correct (for example, you have previously received earnings information from us and it does not agree with your records), we will supply you with more detail for the period in question. Occasionally, earnings amounts are wrong because an employer did not correctly report earnings or earnings are credited to the wrong person. In situations like these, we will send you detailed information, at no charge, so we can correct your record.

  Be sure to show the year(s) involved on the request form and explain why you need the information. If you do not tell us why you need the information, we will charge a fee.

  We will certify the detailed earnings information for an additional fee of $15.00. Certification is usually not necessary unless you plan to use the information in court.

  2. Certified Yearly Totals of Earnings

  Yes, there is a fee of $15 to certify yearly totals of earnings. Certification is usually not necessary unless you plan to use the information in court.

  3. Method of Payment

  Enclose a check or money order for the entire fee required. Payment can also be made by credit card. To do so, complete page 4 of this form and return it with your request form.

REQUEST FOR SOCIAL SECURITY EARNINGS INFORMATION

1. From whose record do you need the earnings information?

Print the Name, Social Security Number (SSN), and date of birth below.

Name _____ Social Security Number _____

Other Name(s) Used (Include Maiden Name) _____ Date of Birth (Mo/Day/Yr) _____

2. What kind of information do you need?

☐ **Detailed Earnings Information** (If you check this block, tell us below why you need this information.) For the period(s)/year(s): _____

_____

_____

☐ **Certified Yearly Totals of Earnings (Check this box only if you want the information certified. Otherwise, call 1-800-772-1213 to request Form SSA-7004, Request for Social Security Statement)** **For the year(s):** _____

3. If you owe us a fee for this detailed earnings information, enter the amount due using the chart on page 3 . . . . . A. $ _____

Do you want us to certify the information? ☐ Yes ☐ No

If yes, enter $15.00 . . . . . B. $ _____

ADD the amounts on lines A and B, and enter the TOTAL amount . . . . . C. $ _____

- You can pay by CREDIT CARD by completing and returning the form on page 4, or
- Send your CHECK or MONEY ORDER for the amount on line C with the request and make check or money order payable to "Social Security Administration"
- DO NOT SEND CASH.

4. I am the individual to whom the record pertains (or a person who is authorized to sign on behalf of that individual). I understand that any false representation to knowingly and willfully obtain information from Social Security records is punishable by a fine of not more than $5,000 or one year in prison.

SIGN your name here (Do not print) > _____ Date _____

Daytime Phone Number _____ _____
(Area Code) (Telephone Number)

5. Tell us where you want the information sent. (Please print)

Name _____ Address _____

City, State & Zip Code _____

6. Mail Completed Form(s) To:

Social Security Administration
Division of Earnings Record Operations
P.O. Box 33003
Baltimore, Maryland 21290-3003

Exception: If using private contractor (e.g., FedEx) to mail form(s), use:

Social Security Administration
Division of Earnings Record Operations
300 N. Greene St.
Baltimore, Maryland 21290-0300

REQUEST FOR SOCIAL SECURITY EARNINGS INFORMATION

How Much Do I Have to Pay For Detailed Earnings?

1. Count the number of years for which you need detailed earnings information. Be sure to add in both the first and last year requested. However, do not add in the current calendar year since this information is not yet available.

2. Use the chart below to determine the correct fee.

Number of Years Requested	Fee	Number of Years Requested	Fee	Number of Years Requested	Fee
1	$15.00	15	$ 43.75	28	$ 64.50
2	17.50	16	45.50	29	66.00
3	20.00	17	47.25	30	67.50
4	22.50	18	49.00	31	68.75
5	25.00	19	50.75	32	70.00
6	27.00	20	52.50	33	71.25
7	29.00	21	54.00	34	72.50
8	31.00	22	55.50	35	73.75
9	33.00	23	57.00	36	75.00
10	35.00	24	58.50	37	76.25
11	36.75	25	60.00	38	77.50
12	38.50	26	61.50	39	78.75
13	40.25	27	63.00	40	80.00
14	42.00				

For Requests Over 40 Years, Please Add 1 Dollar for Each Additional Year.

- **Whose Earnings Can Be Requested**

1. Your Earnings

You can request earnings information from your own record by completing the attached form; we need your handwritten signature. If you sign with an "X", your mark must be witnessed by two disinterested persons who must sign their name and address.

2. Someone Else's Earnings

You can request earnings information from the record of someone else if that person tells us in writing to give the information to you. This writing or "authorization" must be presented to us within 60 days of the date it was signed by that person.

3. A Deceased Person's Earnings

You can request earnings information from the record of a deceased person if you are the legal representative of the estate, a survivor (that is, the spouse, parent, child, divorced spouse of divorced parent), or an individual with a material interest (example-financial) who is an heir at law, next of kin, beneficiary under the will or donee of property of the decedent.

Proof of death must be included with your request. Proof of appointment as representative or proof of your relationship to the deceased must also be included.

YOU CAN MAKE YOUR PAYMENT BY CREDIT CARD

As a convenience, we offer you the option to make your payment by credit card. However, regular credit card rules will apply. You may also pay by check or money order.

Please fill in all the information below and return this form along with your request to:

Social Security Administration
Division of Earnings Record Operations
P.O. Box 33003
Baltimore, Maryland 21290-3003

Exception:
If using private contractor (e.g., FedEx) to mail form(s), use:

Social Security Administration
Division of Earnings Record Operations
300 N. Greene St.
Baltimore, Maryland 21290-0300

Note: Please read Paperwork/Privacy Act Notice

CHECK ONE →	☐ Visa ☐ American Express ☐ MasterCard ☐ Discover ☐ Diners Card
Credit Card Holder's Name → (Enter the name from the credit card)	First Name, Middle Initial, Last Name
Credit Card Holder's Address →	Number & Street City, State, & Zip Code
Daytime Telephone Number →	Area Code / Telephone Number
Credit Card Number →	-- -- --
Credit Card Expiration Date →	Month / Year
Amount Charged →	$
Credit Card Holder's Signature →	

DO NOT WRITE IN THIS SPACE OFFICE USE ONLY	Authorization	
	Name	Date
	Remittance Control #	

PRIVACY ACT NOTICE

The Social Security Administration (SSA) has authority to collect the information requested on this form under section 205 of the Social Security Act. Giving us this information is voluntary. You do not have to do it. We will need this information only if you choose to make payment by credit card. You do not need to fill out this form if you choose another means of payment (for example, by check or money order).

If you choose the credit card payment option, we will provide the information you give us to the banks handling your credit card account and SSA's account. We may also provide this information to another person or government agency to comply with federal laws requiring the release of information from our records. You can find these and other routine uses of information provided to SSA listed in the Federal Register. If you want more information about this, you may call or write any Social Security Office.

Form **8821**

(Rev. October 2012)

Department of the Treasury
Internal Revenue Service

Tax Information Authorization

▶ **Information about Form 8821 and its instructions is at *www.irs.gov/form8821*.**
▶ **Do not sign this form unless all applicable lines have been completed.**
▶ **To request a copy or transcript of your tax return, use Form 4506, 4506-T, or 4506T-EZ.**

OMB No. 1545-1165

For IRS Use Only
Received by:
Name
Telephone
Function
Date

1 Taxpayer information. Taxpayer must sign and date this form on line 7.

Taxpayer name and address (type or print)	**Taxpayer identification number(s)**	
	Daytime telephone number	Plan number (if applicable)

2 Appointee. If you wish to name more than one appointee, attach a list to this form.

Name and address	
	CAF No.
	PTIN
	Telephone No.
	Fax No.
	Check if new: Address ☐ Telephone No. ☐ Fax No. ☐

3 Tax matters. The appointee is authorized to inspect and/or receive confidential tax information for the tax matters listed on this line. Do not use Form 8821 to request copies of tax returns.

(a) Type of Tax (Income, Employment, Payroll, Excise, Estate, Gift, Civil Penalty, etc.) (see instructions)	**(b)** Tax Form Number (1040, 941, 720, etc.)	**(c)** Year(s) or Period(s) (see the instructions for line 3)	**(d)** Specific Tax Matters (see instr.)

4 Specific use not recorded on Centralized Authorization File (CAF). If the tax information authorization is for a specific use not recorded on CAF, check this box. See the instructions. If you check this box, skip lines 5 and 6 . . . . . ▶ ☐

5 Disclosure of tax information (you **must** check a box on line 5a or 5b unless the box on line 4 is checked):

a If you want copies of tax information, notices, and other written communications sent to the appointee on an ongoing basis, check this box . . . . . ▶ ☐

Note. Appointees will no longer receive forms, publications and other related materials with the notices.

b If you do not want any copies of notices or communications sent to your appointee, check this box . . . . . ▶ ☐

6 Retention/revocation of tax information authorizations. This tax information authorization automatically revokes all prior authorizations for the same tax matters you listed on line 3 above unless you checked the box on line 4. If you do not want to revoke a prior tax information authorization, you **must** attach a copy of any authorizations you want to remain in effect **and** check this box . . . . . ▶ ☐

To revoke this tax information authorization, see the instructions.

7 Signature of taxpayer. If signed by a corporate officer, partner, guardian, executor, receiver, administrator, trustee, or party other than the taxpayer, I certify that I have the authority to execute this form with respect to the tax matters and tax periods shown on line 3 above.

▶ IF NOT SIGNED AND DATED, THIS TAX INFORMATION AUTHORIZATION WILL BE RETURNED.

▶ DO NOT SIGN THIS FORM IF IT IS BLANK OR INCOMPLETE.

Signature | Date

Print Name | Title (if applicable)

☐ ☐ ☐ ☐ ☐ PIN number for electronic signature

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form 8821 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/form8821*.

Purpose of Form

Form 8821 authorizes any individual, corporation, firm, organization, or partnership you designate to inspect and/or receive your confidential information for the type of tax and the years or periods you list on Form 8821. You may file your own tax information authorization without using Form 8821, but it must include all the information that is requested on Form 8821.

Form 8821 does not authorize your appointee to advocate your position with respect to federal tax laws; to execute waivers, consents, or closing agreements; or to otherwise represent you before the IRS. If you want to authorize an individual to represent you, use Form 2848, Power of Attorney and Declaration of Representative.

Use Form 4506, Request for Copy of Tax Return, to get a copy of your tax return.

Use Form 4506-T, Request for Transcript of Tax Return, to order: (a) transcript of tax account information and (b) Form W-2 and Form 1099 series information.

Use Form 4506T-EZ, Short Form Request for Individual Tax Return Transcript, to request a tax return transcript for the current and three prior tax years that includes most lines of the original return. The transcript will not show payments, penalty assessments, or adjustments made to the originally filed return.

Use Form 56, Notice Concerning Fiduciary Relationship, to notify the IRS of the existence of a fiduciary relationship. A fiduciary (trustee, executor, administrator, receiver, or guardian) stands in the position of a taxpayer and acts as the taxpayer. Therefore, a fiduciary does not act as an appointee and should not file Form 8821. If a fiduciary wishes to authorize an appointee to inspect and/or receive confidential tax information on behalf of the fiduciary, Form 8821 must be filed and signed by the fiduciary acting in the position of the taxpayer.

When To File

Form 8821 must be received by the IRS within 120 days of the date it was signed and dated by the taxpayer.

Where To File

Generally, mail or fax Form 8821 directly to the IRS. See the *Where To File Chart,* below. Exceptions are listed next.

If Form 8821 is for a specific tax matter, mail or fax it to the office handling that matter. For more information, see the instructions for line 4.

Where To File Chart

IF you live in . . .	THEN use this address . . .	Fax Number*
Alabama, Arkansas, Connecticut, Delaware, District of Columbia, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, or West Virginia	Internal Revenue Service Memphis Accounts Management Center PO Box 268, Stop 8423 Memphis, TN 38101-0268	855-214-7519
Alaska, Arizona, California, Colorado, Hawaii, Idaho, Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, Wisconsin, or Wyoming	Internal Revenue Service 1973 N. Rulon White Blvd. MS 6737 Ogden, UT 84404	855-214-7522
All APO and FPO addresses, American Samoa, nonpermanent residents of Guam or the U.S. Virgin Islands**, Puerto Rico (or if excluding income under section 933), a foreign country, U.S. citizens and those filing Form 2555, 2555-EZ, or 4563.	Internal Revenue Service International CAF 2970 Market St. MS 3-E08.123 Philadelphia, PA 19104	855-772-3156

*These numbers may change without notice. For updates to these fax numbers, go to *www.irs.gov/form8821.*

**Permanent residents of Guam should use Department of Taxation, Government of Guam, P.O. Box 23607, GMF, GU 96921; permanent residents of the U.S. Virgin Islands should use: V.I. Bureau of Internal Revenue, 6115 Estate Smith Bay, Suite 225, St. Thomas, V.I. 00802.

Your appointee may be able to file Form 8821 electronically with the IRS from the IRS website. For more information, go to IRS.gov. Under the *for Tax Pros* tab, go to *Other Tools & Information* and click on *Use e-Services for Tax Pros*. If you complete Form 8821 for electronic signature authorization, do not file a Form 8821 with the IRS. Instead, give it to your appointee, who will retain the document.

Taxpayer Identification Number (TIN)

A TIN is used to confirm the identity of a taxpayer and identify the taxpayer's return and return information. It is important that you furnish your correct name, social security number (SSN), individual taxpayer identification number (ITIN), and/or employer identification number (EIN).

Partnership Items

A Tax Matter Partner is authorized to perform certain acts on behalf of an affected partnership. Rules governing the use of Form 8821 do not replace any provisions of law concerning the tax treatment of partnership items.

Appointee Address Change

If your appointee's address changes, a new Form 8821 is not required. The appointee can provide the IRS with the new information by sending written notification of the new address to the location where the Form 8821 was filed. Your appointee must sign and date the written notice.

Specific Instructions

Line 1. Taxpayer Information

Individual. Enter your name, TIN, and your street address in the space provided. Do not enter your appointee's address or post office box. If a return is a joint return, the appointee(s) identified will only be authorized for you. Your spouse, or former spouse, must submit a separate Form 8821 to designate an appointee.

Corporation, partnership, or association. Enter the name, EIN, and business address.

Employee plan or exempt organization. Enter the name, address, and EIN or SSN of the plan sponsor/plan name, exempt organization or bond issuer. Enter the three-digit plan number when applicable. If you are the plan's trustee and you are authorizing the IRS to disclose the tax information of the plan's trust, see the instructions relating to trust.

Trust. Enter the name, title, and address of the trustee, and the name and EIN of the trust.

Estate. Enter the name and address of the estate. If the estate does not have an identification number, enter the decedent's SSN or ITIN.

Line 2. Appointee

Enter your appointee's full name. Use the identical full name on all submissions and correspondence. Enter the nine-digit CAF number for each appointee. If an appointee has a CAF number for any previously filed Form 8821 or power of attorney (Form 2848), use that number. If a CAF number has not been assigned, enter "NONE," and the IRS will issue one directly to your appointee. The IRS does not assign CAF numbers to requests for employee plans and exempt organizations.

If you want to name more than one appointee, indicate so on this line and attach a list of appointees to Form 8821. If more than two appointees are listed and you request copies of notices and communications be sent to your new appointees (see line 5), copies of notices and communications will be sent only to the first two appointees.

Note. Because the IRS will send copies of notices and communications to no more than two persons, if you previously filed a Form 2848, Power of Attorney and Declaration of Representative, for the same tax matters and periods and you requested copies of notices and communications be sent to your representative(s) at that time, requesting your new appointee(s) receive copies of notices and communications may stop notices and communications from being sent to your authorized representative(s).

Check the appropriate box to indicate if either the address, telephone number, or fax number is new.

Line 3. Matters

Enter the type of tax, the tax form number, the years or periods, and the specific matter. Enter "Not applicable," in any of the columns that do not apply.

For example, you may list "Income, 1040" for calendar year "2010" and "Excise, 720" for "2010" (this covers all quarters in 2010). Multiple years or a series of inclusive periods, including quarterly periods, you may list 2008 through (thru or a hyphen) 2010. For example, "2008 thru 2010" or "2nd 2009-3rd 2010." For fiscal years, enter the ending year and month, using the YYYYMM format. Do not use a general reference such as "All years," "All periods," or "All taxes." Any tax information authorization with a general reference will be returned.

You may list the current year or period and any tax years or periods that have already ended as of the date you sign the tax information authorization. However, you may include on a tax information authorization only future tax periods that end no later than 3 years after the date the tax information authorization is received by the IRS. The 3 future periods are determined starting after December 31 of the year the tax information authorization is received by the IRS. You must enter the type of tax, the tax form number, and the future year(s) or period(s). Only tax forms directly related to the taxpayer may be listed on line 3. If the matter relates to estate tax, enter the date of the decedent's death instead of the year or period.

If you appoint someone only with respect to a penalty and interest due on that penalty, enter "civil penalty" in the description of matters column. If applicable, enter the tax year(s) for the penalty. Enter "NA" (not applicable) in the tax form number column. You do not have to enter the specific penalty.

Column (d). Enter any specific information you want the IRS to provide. Examples of column (d) information are: lien information, a balance due amount, a specific tax schedule, or a tax liability. Enter "not applicable" in column (d) if you are not limiting your appointee's authority to inspect and/or receive confidential tax information described in columns (a), (b), and (c).

For requests regarding Form 8802, Application for United States Residency Certification, enter "Form 8802" in column (d) and check the specific use box on line 4. Also, enter the appointee's information as instructed on Form 8802.

Note. If the taxpayer is subject to penalties related to an individual retirement account (IRA) (for example, a penalty for excess contributions) enter, "IRA civil penalty" on line 3, column a.

Note. If Form W-2 is listed on line 3, then the appointee may receive information regarding any civil penalties charged that relate to that Form W-2.

A Form 8821 that lists a particular tax return will also entitle the appointee to receive the taxpayer notices regarding any return-related civil penalties and a specific reference to penalties is not required. However, any civil penalty that is not return-related is not covered by the Form 8821 unless it references "civil penalties" or a specific penalty is stated.

Line 4. Specific Use Not Recorded on CAF

Generally, the IRS records all tax information authorizations on the CAF system. However, authorizations relating to a specific issue are not recorded.

Check the box on line 4 if Form 8821 is filed for any of the following reasons:

(a) requests to disclose information to loan companies or educational institutions,

(b) requests to disclose information to federal or state agency investigators for background checks,

(c) application for EIN, or

(d) claims filed on Form 843, Claim for Refund and Request for Abatement.

If you check the box on line 4, your appointee should mail or fax Form 8821 to the IRS office handling the matter. Otherwise, your appointee should bring a copy of Form 8821 to each appointment to inspect or receive information. A specific-use tax information authorization will not revoke any prior tax information authorizations.

Line 6. Retention/Revocation of Tax Information Authorizations

Check the box on this line and attach a copy of any tax information authorization you do not want to revoke. The filing of Form 8821 will not revoke any Form 2848 that is in effect.

If you want to revoke an existing tax information authorization and do not want to name a new appointee, send a copy of the previously executed tax information authorization to the IRS, using the *Where To File Chart,* earlier. The copy of the tax information authorization must have a current signature of the taxpayer and date under the original signature on line 7. Write "REVOKE" across the top of Form 8821.

If you do not have a copy of the tax information authorization you want to revoke, send a statement to the IRS. In the statement:

(a) indicate that the authority of the appointee is revoked,

(b) list the name and address of each recognized appointee whose authority is revoked,

(c) list the tax matters and tax periods, and

(d) sign and date the statement.

If you are completely revoking the authority of the appointee, state "remove all years/periods" instead of listing the specific tax matters, years, or periods.

To revoke a specific use tax information authorization, send the tax information authorization or statement of revocation to the IRS office handling your case, using the above instructions.

Line 7. Signature of Taxpayer

Individual. You must sign and date the authorization. If a joint return has been filed, your spouse must execute his or her own authorization on a separate Form 8821 to designate an appointee.

Corporation. Generally, Form 8821 can be signed by:

(a) an officer having authority under applicable state law to bind the corporation,

(b) any person designated by the board of directors or other governing body,

(c) any officer or employee on written request by any principal officer and attested to by the secretary or other officer, and

(d) any other person authorized to access information under section 6103(e)(1)(D), except for a person described in section 6103(a)(1)(D)(ii) (bona fide shareholders of record owning 1% or more of the outstanding stock of the corporation).

Partnership. Generally, Form 8821 can be signed by any person who was a member of the partnership during any part of the tax period covered by Form 8821. See *Partnership Items,* earlier. If the Form 8821 covers more than one tax year or tax period, the person must have been a member of the partnership for all or part of each tax year or period covered by Form 8821.

Employee plan. If the plan is listed as the taxpayer on line 1, a duly authorized individual having authority to bind the taxpayer must sign and that individual's exact title must be entered.

If the trust is the taxpayer, listed on line 1, a trustee having the authority to bind the trust must sign with the title of trustee entered. If the trust has not previously submitted a completed Form 56, Notice Concerning Fiduciary Relationship, identifying the current trustee, the trust must submit a Form 56 to identify the current trustee.

Estate. If there is more than one executor, only one executor having the authority to bind the estate is required to sign. See regulations section 601.503(d).

All others. See section 6103(e) if the taxpayer has died, is insolvent, is a dissolved corporation, or if a trustee, guardian, executor, receiver, or administrator is acting for the taxpayer.

Privacy Act and Paperwork Reduction Act Notice

We ask for the information on this form to carry out the Internal Revenue laws of the United States. Form 8821 authorizes the IRS to disclose your confidential tax information to the person you appoint. This form is provided for your convenience and its use is voluntary. The information is used by the IRS to determine what confidential tax information your appointee can inspect and/or receive. Section 6103(c) and its regulations require you to provide this information if you want to designate an appointee to inspect and/or receive your confidential tax information. Under section 6109, you must disclose your identification number. If you do not provide all the information requested on this form, we may not be able to honor the authorization. Providing false or fraudulent information may subject you to penalties.

We may disclose this information to the Department of Justice for civil or criminal litigation, and to cities, states, the District of Columbia, and U.S. commonwealths and possessions for use in administering their tax laws. We may also disclose this information to other countries under a tax treaty, to federal and state agencies to enforce federal nontax criminal laws, or to federal law enforcement and intelligence agencies to combat terrorism.

You are not required to provide the information requested on a form that is subject to the Paperwork Reduction Act unless the form displays a valid OMB control number. Books or records relating to a form or its instructions must be retained as long as their contents may become material in the administration of any Internal Revenue law.

The time needed to complete and file this form will vary depending on individual circumstances. The estimated average time is: **Recordkeeping**, 6 min.; **Learning about the law or the form**, 12 min.; **Preparing the form**, 24 min.; **Copying and sending the form to the IRS**, 20 min.

If you have comments concerning the accuracy of these time estimates or suggestions for making Form 8821 simpler, we would be happy to hear from you. You can write to Internal Revenue Service, Individual and Specialty Forms and Publications Branch, SE:W:CAR:MP:T:I, 1111 Constitution Ave. NW, IR-6526, Washington, DC 20224. **Do not** send Form 8821 to this address. Instead, see the *Where To File Chart,* earlier.

Social Security Administration

Form Approved
OMB No. 0960-0525

REQUEST FOR SOCIAL SECURITY EARNINGS INFORMATION

*Use This Form If You Need

1. Certified/Non-Certified Detailed Earnings Information

Includes periods of employment or self-employment and the names and addresses of employers.

OR

2. Certified Yearly Totals of Earnings

Includes total earnings for each year but does not include the names and addresses of employers.

DO NOT USE THIS FORM FOR:

Non-certified yearly totals of earnings

This service is free to the public.

These totals can be obtained by calling 1-800-772-1213 to receive Form SSA-7004, Request for Social Security Statement

PRIVACY ACT NOTICE: We are authorized to collect this information under section 205 of the Social Security Act, and the Federal Records Act of 1950 (64 Stat. 583). It is needed so we can identify your records and prepare the statement you request. You do not have to furnish the information, but failure to do so may prevent your request from being processed.

Paperwork Reduction Act Statement - This information collection meets the requirements of 44 U.S.C. § 3507, as amended by section 2 of the Paperwork Reduction Act of 1995. You do not need to answer these questions unless we display a valid Office of Management and Budget control number. We estimate that it will take about 11 minutes to read the instructions, gather the facts, and answer the questions. ***Send only comments relating to our time estimate above to:*** SSA, 6401 Security Blvd, Baltimore, MD 21235-6401.

INFORMATION ABOUT YOUR REQUEST

- **How Do I Get This Information?**

  You need to complete the attached form to tell us what information you want.

- **Can I Get This Information For Someone Else?**

  Yes, if you have their written permission. For more information, see page 3.

- **Who Can Sign On Behalf Of The Individual?**

  The parent of a minor child, or the legal guardian of an individual who has been declared legally incompetent, may sign if he/she is acting on behalf of the individual.

- **Is There A Fee For This Information?**

  1. Certified/Non-Certified Detailed Earnings Information

  Yes, we usually charge a fee for detailed information. In most cases, this information is used for purposes NOT directly related to Social Security such as for a private pension plan or personal injury suit. The fee chart on page 3 gives the amount of the charge.

  Sometimes, there is no charge for detailed information. If you have reason to believe your earnings are not correct (for example, you have previously received earnings information from us and it does not agree with your records), we will supply you with more detail for the period in question. Occasionally, earnings amounts are wrong because an employer did not correctly report earnings or earnings are credited to the wrong person. In situations like these, we will send you detailed information, at no charge, so we can correct your record.

  Be sure to show the year(s) involved on the request form and explain why you need the information. If you do not tell us why you need the information, we will charge a fee.

  We will certify the detailed earnings information for an additional fee of $15.00. Certification is usually not necessary unless you plan to use the information in court.

  2. Certified Yearly Totals of Earnings

  Yes, there is a fee of $15 to certify yearly totals of earnings. Certification is usually not necessary unless you plan to use the information in court.

  3. Method of Payment

  Enclose a check or money order for the entire fee required. Payment can also be made by credit card. To do so, complete page 4 of this form and return it with your request form.

REQUEST FOR SOCIAL SECURITY EARNINGS INFORMATION

1. From whose record do you need the earnings information?

Print the Name, Social Security Number (SSN), and date of birth below.

Name _____ Social Security Number _____

Other Name(s) Used (Include Maiden Name) _____ Date of Birth (Mo/Day/Yr) _____

2. What kind of information do you need?

☐ **Detailed Earnings Information** (If you check this block, tell us below why you need this information.) For the period(s)/year(s): _____

_____

_____

☐ **Certified Yearly Totals of Earnings (Check this box only if you want the information certified. Otherwise, call 1-800-772-1213 to request Form SSA-7004, Request for Social Security Statement)** **For the year(s):** _____

3. If you owe us a fee for this detailed earnings information, enter the amount due using the chart on page 3 . . . . . A. $ _____

Do you want us to certify the information? ☐ Yes ☐ No

If yes, enter $15.00 . . . . . B. $ _____

ADD the amounts on lines A and B, and enter the TOTAL amount . . . . . C. $ _____

- You can pay by CREDIT CARD by completing and returning the form on page 4, or
- Send your CHECK or MONEY ORDER for the amount on line C with the request and make check or money order payable to "Social Security Administration"
- DO NOT SEND CASH.

4. I am the individual to whom the record pertains (or a person who is authorized to sign on behalf of that individual). I understand that any false representation to knowingly and willfully obtain information from Social Security records is punishable by a fine of not more than $5,000 or one year in prison.

SIGN your name here (Do not print) > _____ Date _____

Daytime Phone Number _____ _____
(Area Code) (Telephone Number)

5. Tell us where you want the information sent. (Please print)

Name _____ Address _____

City, State & Zip Code _____

6. Mail Completed Form(s) To:

Social Security Administration
Division of Earnings Record Operations
P.O. Box 33003
Baltimore, Maryland 21290-3003

Exception: If using private contractor (e.g., FedEx) to mail form(s), use:

Social Security Administration
Division of Earnings Record Operations
300 N. Greene St.
Baltimore, Maryland 21290-0300

REQUEST FOR SOCIAL SECURITY EARNINGS INFORMATION

How Much Do I Have to Pay For Detailed Earnings?

1. Count the number of years for which you need detailed earnings information. Be sure to add in both the first and last year requested. However, do not add in the current calendar year since this information is not yet available.

2. Use the chart below to determine the correct fee.

Number of Years Requested	Fee	Number of Years Requested	Fee	Number of Years Requested	Fee
1	$15.00	15	$ 43.75	28	$ 64.50
2	17.50	16	45.50	29	66.00
3	20.00	17	47.25	30	67.50
4	22.50	18	49.00	31	68.75
5	25.00	19	50.75	32	70.00
6	27.00	20	52.50	33	71.25
7	29.00	21	54.00	34	72.50
8	31.00	22	55.50	35	73.75
9	33.00	23	57.00	36	75.00
10	35.00	24	58.50	37	76.25
11	36.75	25	60.00	38	77.50
12	38.50	26	61.50	39	78.75
13	40.25	27	63.00	40	80.00
14	42.00				

For Requests Over 40 Years, Please Add 1 Dollar for Each Additional Year.

- **Whose Earnings Can Be Requested**

1. Your Earnings

You can request earnings information from your own record by completing the attached form; we need your handwritten signature. If you sign with an "X", your mark must be witnessed by two disinterested persons who must sign their name and address.

2. Someone Else's Earnings

You can request earnings information from the record of someone else if that person tells us in writing to give the information to you. This writing or "authorization" must be presented to us within 60 days of the date it was signed by that person.

3. A Deceased Person's Earnings

You can request earnings information from the record of a deceased person if you are the legal representative of the estate, a survivor (that is, the spouse, parent, child, divorced spouse of divorced parent), or an individual with a material interest (example-financial) who is an heir at law, next of kin, beneficiary under the will or donee of property of the decedent.

Proof of death must be included with your request. Proof of appointment as representative or proof of your relationship to the deceased must also be included.

YOU CAN MAKE YOUR PAYMENT BY CREDIT CARD

As a convenience, we offer you the option to make your payment by credit card. However, regular credit card rules will apply. You may also pay by check or money order.

Please fill in all the information below and return this form along with your request to:

Social Security Administration
Division of Earnings Record Operations
P.O. Box 33003
Baltimore, Maryland 21290-3003

Exception:
If using private contractor (e.g., FedEx) to mail form(s), use:

Social Security Administration
Division of Earnings Record Operations
300 N. Greene St.
Baltimore, Maryland 21290-0300

Note: Please read Paperwork/Privacy Act Notice

CHECK ONE →	☐ Visa ☐ American Express ☐ MasterCard ☐ Discover ☐ Diners Card
Credit Card Holder's Name → (Enter the name from the credit card)	First Name, Middle Initial, Last Name
Credit Card Holder's Address →	Number & Street City, State, & Zip Code
Daytime Telephone Number →	Area Code ___ Telephone Number
Credit Card Number →	____ -- ____ -- ____ -- ____
Credit Card Expiration Date →	Month ___ Year
Amount Charged →	$
Credit Card Holder's Signature →	

DO NOT WRITE IN THIS SPACE
OFFICE USE ONLY

Authorization

Name | Date

Remittance Control #

PRIVACY ACT NOTICE

The Social Security Administration (SSA) has authority to collect the information requested on this form under section 205 of the Social Security Act. Giving us this information is voluntary. You do not have to do it. We will need this information only if you choose to make payment by credit card. You do not need to fill out this form if you choose another means of payment (for example, by check or money order).

If you choose the credit card payment option, we will provide the information you give us to the banks handling your credit card account and SSA's account. We may also provide this information to another person or government agency to comply with federal laws requiring the release of information from our records. You can find these and other routine uses of information provided to SSA listed in the Federal Register. If you want more information about this, you may call or write any Social Security Office.

INSTRUCTION AND INFORMATION SHEET FOR SF 180, REQUEST PERTAINING TO MILITARY RECORDS

1. General Information. The Standard Form 180, Request Pertaining to Military Records (SF180) is used to request information from military records. Certain identifying information is necessary to determine the location of an individual's record of military service. Please try to answer each item on the SF 180. If you do not have and cannot obtain the information for an item, show "NA," meaning the information is "not available." Include as much of the requested information as you can. Incomplete information may delay response time. To determine where to mail this request see Page 2 of the SF180 for record locations and facility addresses.

Online requests may be submitted to the National Personnel Records Center (NPRC) by a veteran or deceased veteran's next of kin using eVetRecs at http://www.archives.gov/veterans/military-service-records/.

2. Personnel Records/Military Human Resource Records/Official Military Personnel File (OMPF) and Medical Records/Service Treatment Records (STR). Personnel records of military members who were discharged, retired, or died in service **less than 62 years** ago and medical records are in the legal custody of the military service department and are administered in accordance with rules issued by the Department of Defense and the Department of Homeland Security (DHS, Coast Guard). STR's of persons on active duty are generally kept at the local servicing clinic, and usually are available from the Department of Veterans Affairs approximately 40 days after the last day of active duty. (See item 3, Archival Records, if the military member was discharged, retired or died in service over 62 years ago.)

a. Release of information: Release of information is subject to restrictions imposed by the military services consistent with Department of Defense regulations and the provisions of the Freedom of Information Act (FOIA) and the Privacy Act of 1974. The service member (either past or present) or the member's legal guardian has access to almost any information contained in that member's own record. An authorization signature, of the service member or the member's legal guardian, is needed in Section III of the SF180. Others requesting information from military personnel records and/or STR's must have the release authorization in Section III of the SF 180 signed by the member or legal guardian. If the appropriate signature cannot be obtained, only limited types of information can be provided. If the former member is deceased, surviving next of kin may, under certain circumstances, be entitled to greater access to a deceased veteran's records than a member of the general public. The next of kin may be any of the following: unremarried surviving spouse, father, mother, son, daughter, sister, or brother. Requesters **must provide proof of death, such as a copy of a death certificate, newspaper article (obituary) or death notice, coroner's report of death; funeral director's signed statement of death, or verdict of coroner's jury.**

b. Fees for records: There is no charge for most services provided to service members or next of kin of deceased veterans. A nominal fee is charged for certain types of service. In most instances service fees cannot be determined in advance. If your request involves a service fee, you will be notified.

3. Archival Records. Personnel records of military members who were discharged, retired, or died in service **62 or more years** ago have been transferred to the legal custody of NARA and are referred to as "archival" records.

a. Release of Information: Archival records are open to the public. The Privacy Act of 1974 does not apply to archival records, therefore, written authorization from the veteran or next of kin is not required. However, in order to protect the privacy of the veteran, his/her family, and third parties named in the records, the personal privacy exemption of the Freedom of Information Act (5 U.S.C. 552 (b) (6)) may still apply and preclude the release of some information.

b. Fees for Archival Records: Access to archival records is granted by offering copies of the records for a fee (44 U.S.C. 2116 (c)). You will be notified if there is a charge for photocopies of documents contained in the record you are requesting. For more information see http://www.archives.gov/st-louis/archival-programs/military-personnel-archival/ompf-archival-requests.html.

4. Where reply may be sent. The reply may be sent to the service member or any other address designated by the service member or other authorized requester.

5. Definitions and abbreviations. DISCHARGED -- the individual has no current military status; SERVICE TREATMENT RECORD (STR) -- The chronology of medical, mental health and dental care received by service members during the course of their military career (does not include records of treatment while hospitalized); TDRL – Temporary Disability Retired List.

6. Service completed before World War I. National Archives Trust Fund (NATF) forms must be used to request these records. Obtain the forms by e-mail from *inquire@nara.gov* or write to the Code 6 address on page 2 of the SF 180.

PRIVACY ACT OF 1974 COMPLIANCE INFORMATION

The following information is provided in accordance with 5 U.S.C. 552a(e)(3) and applies to this form. Authority for collection of the information is 44 U.S.C. 2907, 3101, and 3103, and Public Law 104-134 (April 26, 1996), as amended in title 31, section 7701. Disclosure of the information is voluntary. If the requested information is not provided, it may delay servicing your inquiry because the facility servicing the service member's record may not have all of the information needed to locate it. The purpose of the information on this form is to assist the facility servicing the records (see the address list) in locating the correct military service record(s) or information to answer your inquiry. This form is then retained as a record of disclosure. The form may also be disclosed to Department of Defense components, the Department of Veterans Affairs, the Department of Homeland Security (DHS, U.S. Coast Guard), or the National Archives and Records Administration when the original custodian of the military health and personnel records transfers all or part of those records to that agency. If the service member was a member of the National Guard, the form may also be disclosed to the Adjutant General of the appropriate state, District of Columbia, or Puerto Rico, where he or she served.

PAPERWORK REDUCTION ACT PUBLIC BURDEN STATEMENT

Public burden reporting for this collection of information is estimated to be five minutes per request, including time for reviewing instructions and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden, to National Archives and Records Administration (NHP), 8601 Adelphi Road, College Park, MD 20740-6001. DO NOT SEND COMPLETED FORMS TO THIS ADDRESS. SEND COMPLETED FORMS AS INDICATED IN THE ADDRESS LIST ON PAGE 2 OF THE SF 180.

Standard Form 180 (Rev. 5/12) (Page 1)
Prescribed by NARA (36 CFR 1228.168(b))

Authorized for local reproduction
Previous edition unusable

OMB No. 3095-0029 Expires 01/31/2015

REQUEST PERTAINING TO MILITARY RECORDS

* Requests from veterans or deceased veteran's next-of-kin may be submitted online by using eVetRecs at http://www.archives.gov/veterans/military-service-records/*

(To ensure the best possible service, please thoroughly review the accompanying instructions before filling out this form. Please print clearly or type.)

SECTION I - INFORMATION NEEDED TO LOCATE RECORDS (Furnish as much as possible.)

1. NAME USED DURING SERVICE (last, first, and middle)	2. SOCIAL SECURITY NO.	3. DATE OF BIRTH	4. PLACE OF BIRTH

5. SERVICE, PAST AND PRESENT (For an effective records search, it is important that all service be shown below.)

	BRANCH OF SERVICE	DATE ENTERED	DATE RELEASED	OFFICER	ENLISTED	SERVICE NUMBER (If unknown, write "unknown")
a. ACTIVE COMPONENT						
b. RESERVE COMPONENT						
c. NATIONAL GUARD						

6. IS THIS PERSON DECEASED? If "YES" enter the date of death.
☐ NO ☐ YES _____

7. IS (WAS) THIS PERSON RETIRED FROM MILITARY SERVICE?
☐ NO ☐ YES

SECTION II – INFORMATION AND/OR DOCUMENTS REQUESTED

1. CHECK THE ITEM(S) YOU ARE REQUESTING:

☐ **DD Form 214 or equivalent.** When was the DD Form(s) 214 issued? YEAR(S): _____
If more than one period of service was performed, even in the same branch, there may be more than one DD214.

This form contains information normally needed to verify military service. A copy may be sent to the veteran, the deceased veteran's next of kin, or other persons or organizations if authorized in Section III, below. **An UNDELETED DD214 is ordinarily required to determine eligibility for benefits.** Sensitive items, such as, the character of separation, authority for separation, reason for separation, reenlistment eligibility code, separation (SPD/SPN) code, and dates of time lost are usually shown.

An undeleted copy will be sent unless you specify a deleted copy. Indicate here if you want a deleted copy of the DD Form 214 . ☐.

The following items are deleted: authority for separation, reason for separation, reenlistment eligibility code, separation (SPD/SPN) code, and for separations after June 30, 1979, character of separation and dates of time lost.

☐ **All Documents in Official Military Personnel File (OMPF)**

☐ **Medical Records** (Includes Service Treatment Records, Health (outpatient) and dental records.) If hospitalized (inpatient), the facility name and date for each admission **must** be provided: _____

☐ **Other** (Specify): _____

2. PURPOSE: (An explanation of the purpose of the request is **strictly voluntary**; however, such information may help to provide the best possible response and may result in a faster reply. Information provided will in no way be used to make a decision to deny the request.) Check appropriate box:

☐ Benefits ☐ Employment ☐ VA Loan Programs ☐ Medical ☐ Genealogy ☐ Correction ☐ Personal

☐ Other, explain: _____

SECTION III - RETURN ADDRESS AND SIGNATURE

1. REQUESTER IS: (*Signature Required in # 3 below of veteran, next of kin, legal guardian, authorized government agent or "other" authorized representative. If "other" authorized representative, provide copy of authorization letter.) No signature required for Archival records.*

☐ Military service member or veteran identified in Section I, above
☐ Next of kin of deceased veteran: _____ *(Relationship)*
☐ Legal guardian (Must submit copy of court appointment.)
☐ Other (specify) _____

MUST HAVE PROOF OF DEATH - See item 2a on instruction sheet.

2. SEND INFORMATION/DOCUMENTS TO:
(Please print or type. See item 4 on accompanying instructions.)

Name _____

Street _____ Apt. _____

City _____ State _____ Zip Code _____

3. AUTHORIZATION SIGNATURE WHEN REQUIRED *(See items 2a or 3a on accompanying instructions.)* I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the information in this Section III is true and correct. No signature required for Archival records.

Signature Required - Do not print _____ **Date** _____

( ) Daytime phone _____ ( ) Fax Number _____

Email address _____

*This form is available at *http://www.archives.gov/research/order/standard-form-180.pdf* on the National Archives and Records Administration (NARA) web site.*

Standard Form 180 (Rev. 5/12) (Page 2)
Prescribed by NARA (36 CFR 1228.168(b))
Authorized for local reproduction
Previous edition unusable
OMB No. 3095-0029 Expires 01/31/2015

LOCATION OF MILITARY RECORDS

The various categories of military service records are described in the chart below. For each category there is a code number which indicates the address at the bottom of the page to which this request should be sent. Please refer to the Instruction and Information Sheet accompanying this form as needed.

BRANCH	CURRENT STATUS OF SERVICE MEMBER	ADDRESS CODE	
		Personnel Record	Medical or Service Treatment Record
AIR FORCE	Discharged, deceased, or retired before 5/1/1994	14	14
	Discharged, deceased, or retired 5/1/1994 – 9/30/2004	14	11
	Discharged, deceased, or retired on or after 10/1/2004	1	11
	Active (including National Guard on active duty in the Air Force), TDRL, or general officers retired with pay	1	
	Reserve, retired reserve in nonpay status, current National Guard officers not on active duty in the Air Force, or National Guard released from active duty in the Air Force	2	
	Current National Guard enlisted not on active duty in the Air Force	13	
COAST GUARD	Discharge , deceased, or retired before 1/1/1898	6	
	Discharged, deceased, or retired 1/1/1898 – 3/31/1998	14	14
	Discharged, deceased, or retired on or after 4/1/1998	14	11
	Active, reserve, or TDRL	3	
MARINE CORPS	Discharged, deceased, or retired before 1/1/1905	6	
	Discharged, deceased, or retired 1/1/1905 – 4/30/1994	14	14
	Discharged, deceased, or retired 5/1/1994 – 12/31/1998	14	11
	Discharged, deceased, or retired on or after 1/1/1999	4	11
	Individual Ready Reserve	5	
	Active, Selected Marine Corps Reserve, TDRL	4	
ARMY	Discharged, deceased, or retired before 11/1/1912 (enlisted) or before 7/1/1917 (officer)	6	
	Discharged, deceased, or retired 11/1/1912 – 10/15/1992 (enlisted) or 7/1/1917 – 10/15/1992 (officer)	14	
	Discharged, deceased, or retired after 10/16/1992	14	11
	Active enlisted, officers	7	
	Former National Guard/USAR personnel	14	
NAVY	Discharged, deceased, or retired before 1/1/1886 (enlisted) or before 1/1/1903 (officer)	6	
	Discharged, deceased, or retired 1/1/1886 – 1/30/1994 (enlisted) or 1/1/1903 – 1/30/1994 (officer)	14	14
	Discharged, deceased, or retired 1/31/1994 – 12/31/1994	14	11
	Discharged, deceased, or retired on or after 1/1/1995	10	11
	Active, reserve, or TDRL	10	
PHS	Public Health Service - Commissioned Corps officers only	12	

ADDRESS LIST OF CUSTODIANS (BY CODE NUMBERS SHOWN ABOVE) – Where to write/send this form

1	Air Force Personnel Center HQ AFPC/DPSIRP 550 C Street West, Suite 19 Randolph AFB, TX 78150-4721	6	National Archives & Records Administration Old Military and Civil Records (NWCTB-Military) Textual Services Division 700 Pennsylvania Ave., N.W. Washington, DC 20408-0001	11	Department of Veterans Affairs Records Management Center P.O. Box 5020 St. Louis, MO 63115-5020
2	Air Reserve Personnel Center Records Management Branch (DPTARA) 18420 E. Silver Creek Ave. Bldg. 390 MS 68 Buckley AFB, CO 80011	7	US Army Human Resources Command ATTN: AHRC-PDR-V 1600 Spearhead Division Ave., Dept 420 Fort Knox, KY 40122-5402 askhrc.army@us.army.mil	12	Division of Commissioned Corps Officer Support ATTN: Records Officer 1101 Wooton Parkway, Plaza Level, Suite 100 Rockville, MD 20852
3	Commander, Personnel Service Center (PSD-MR) MS7200 US Coast Guard 4200 Wilson Blvd., Suite 1100 Arlington, VA 29598-7200 http://uscg.mil/psc/adm	8	*Reserved.*	13	*Reserved.*
4	Headquarters U.S. Marine Corps Manpower Management Support Branch (MMSB-10) 2008 Elliot Road Quantico, VA 22134-5030	9	*Reserved.*	14	National Personnel Records Center (Military Personnel Records) 1 Archives Dr. St. Louis, MO 63138-1002 *e*VetRecs! *http://www.archives.gov/veterans/military-service-records/*
5	Marine Forces Reserve 4400 Dauphine St. New Orleans, LA 70146-5400	10	Navy Personnel Command (PERS-312E) 5720 Integrity Drive Millington, TN 38055-3120		

EXHIBIT C

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------x

IN RE PROPECIA (FINASTERIDE)
PRODUCT LIABILITY LITIGATION 12-MDL-2331 (JG)(VVP)

----------x

THIS DOCUMENT APPLIES TO:

Judge John Gleeson
Judge Viktor Poherelsky

ALL CASES

----------x

PRACTICE AND PROCEDURE ORDER NO. 6
(DEPOSITION PROTOCOL)

Depositions shall be governed by the following terms:

1. Deposition Notices.

A. All depositions in 12-MDL-2331 (JG)(VVP), except pursuant to Court order, will be noticed and conducted pursuant to Fed. R. Civ. P. 30.

B. A Deposition Notice may be cross-noticed in any Propecia (Finasteride) action pending in a state court.

C. Deposition Notices shall be in a form consistent with the Rules of Civil Procedure and shall note whether the deposition is to be videotaped.

D. Any Deposition Notice served pursuant to Fed. R. Civ. P. 45 will attach this Deposition Protocol.

2. Cooperation.

Counsel are expected to cooperate with, and be courteous to, all counsel and deponents.

3. Scheduling.

A. Depositions shall be scheduled at least thirty (30) days in advance absent extraordinary circumstances. However, Counsel shall work in good faith to accommodate a particular witness' professional schedule.

B. More than one deposition may take place in 12-MDL-2331 (JG)(VVP) at the same time, except that no more than two (2) depositions may be scheduled by any Party for deposition on the same day absent agreement by the Parties or by Order of the Court. Counsel shall endeavor to act in good faith so as not to schedule an unreasonable number of depositions on the same day or in disparate parts of the Country. The Parties reserve the right to file a motion for a protective order and to quash any deposition notice.

4. Locations for Taking Depositions.

A. Unless otherwise agreed by Liaison Counsel, depositions of plaintiffs will take place in the Plaintiff's locale or by agreement of the Parties in a metropolitan city with a major airport closest to each plaintiff's residence.

B. Unless otherwise agreed by the Plaintiffs' Executive Committee and Merck's Counsel, depositions of Merck current employees, past employees that are represented by Defense Counsel or past employees who are represented by Butler Snow and voluntarily agree to appear will take place in one of the following locations:

- Brooklyn, New York;
- Princeton, New Jersey; or
- Philadelphia, Pennsylvania.

C. Unless otherwise agreed by Liaison Counsel, the deposition of an expert witness shall take place in the expert witness' home district.

D. Depositions of defendants other than Merck and non-party witnesses, excluding expert witnesses, will take place in a location agreed upon by the Parties.

5. Deposition Week.

In any week in which depositions will be taken, such depositions shall commence no earlier than 9:00 a.m. on Monday and end no later than 3:00 p.m. on Friday of that week, unless by agreement of the Parties.

6. Attendance.

A. *Who May be Present*. Unless otherwise agreed to by the Plaintiffs' Executive Committee or Lead Defense Counsel, depositions may be attended only by the Parties, the deponent, the deponent's attorney, attorneys of record in 12-MDL-2331 (JG(VVP)) or state Propecia (Finasteride) cases (including any employee or retained consultant of such attorney who is assisting in the litigation and whose presence is reasonably required by the attorney), in-house counsel for Merck, the court reporter, and the videographer. For good cause shown, the Court may permit attendance by a person who does not fall within any of these categories.

B. *Use of Confidential Documents*. Use of confidential documents and/or confidential information shall be used in accordance with the Stipulation and Order Regarding Confidential Information entered in this MDL 12-MDL-2331 (JG)(VVP).

7. Conduct of the Deposition.

Except by order of the Court, the following provision shall apply at all depositions of fact witnesses:

A. *Selection of Attorneys to Conduct Examination and Length of Deposition.*

(1) One attorney will conduct the principal examination of the deponent on behalf of: (i) the Plaintiffs' Steering Committee; (ii) plaintiffs in state court actions;

and (iii) of Merck. The attorney so designated by the Plaintiffs' Steering Committee will cooperate with other plaintiffs' counsel reasonably in advance of the date scheduled for the deposition regarding the areas of examination in order to conduct a thorough examination.

(2) In some depositions there may be sufficient divergence of positions among parties on the same side of the case such that additional examiners may be appropriate on non-redundant (i.e., new) subject matters, in which event other attorneys will be permitted to examine deponents on non-redundant matters. Additionally, witnesses may present testimony that is complex and across different subject matter areas that may also require additional examiners on non-redundant matters, *e.g.*, expert witnesses testifying on general causation. The need for additional examiners and the non-redundant requirement will be strictly construed. The Plaintiffs' Steering Committee at its discretion may have more than one questioner on unrelated topics. However, the addition of a second questioner shall not expand the time for questioning or allow for repetitive questioning.

B. Objections.

(1) All objections as to relevance and admissibility shall be preserved for later ruling by the Court. Any objection to evidence during a deposition shall be stated concisely and in a non-argumentative and non-suggestive manner.

(2) Speaking objections are prohibited.

(3) The use of the word "objection" shall be deemed to preserve all possible objections to the form of the question or the responsiveness of the answer. An objection made by one party shall inure to the benefit of all Parties.

C. *Directions Not to Answer*. A party may instruct a deponent not to answer only when necessary to preserve a privilege, to endorse a limitation on evidence directed by the Court, or to present a motion.

D. *Objections to Documents*. Objections to the admissibility of documents are not waived and are reserved for later ruling by the Court or trial judge. A party need not "move" the admittance of a document in a deposition to preserve its use trial.

E. *Sequence of Examination — Depositions Taken by Plaintiffs.*

Questioning at the depositions to be taken by plaintiffs will be conducted in the following sequence:

(1) the primary examiner selected by the Plaintiffs' Steering Committee – which may include a lawyer from the State Court Litigants;

(2) other 12-MDL-2331 (JG)(VVP) plaintiffs' attorneys on non-redundant matters;

(3) the primary examiner selected by the State Court Litigants if not the primary questioner in the deposition;

(4) the primary examiner selected by Merck;

(5) individual counsel for the deponent, if any; and

(6) any recross or redirect by 1-5, *supra.*

F. *Sequence of Examination — Depositions Taken by Merck.*

Questioning at the depositions taken by defendants shall be conducted in the following sequence:

(1) the primary examiner selected by Merck;

(2) any other 12-MDL-2331(JG)(VVP) defendant's attorney on non-redundant matters;

(3) the primary examiner selected by Plaintiffs' Steering Committee – which may include a lawyer from the State Court Litigants;

(4) any other 12-MDL-2331(JG)(VVP) plaintiffs' attorney on non-redundant matters;

(5) the primary examiner selected by the State Court litigants if not the primary questioner in the deposition;

(6) individual counsel for the deponent, if any; and

(7) any recross and redirect by 1-6, supra.

G. *Length of Depositions*: The time limitations imposed by Fed. R. Civ. P. 30(d)(1) shall apply in the MDL unless the Parties agree to a different time limitation or the Court establishes a different time limitation. In the event a Party desires to take a witness's deposition for more than the time set forth above, the Parties shall meet and confer to negotiate the appropriateness of additional time. If the Parties are unable to agree, the Party requesting the additional time may move the Court for an Order granting the additional time.

8. Subpoenas and Documents.

A. *Subpoenas Pre-Notice*. Prior to serving a subpoena pursuant to Rule 45 of the Fed. R. Civ. P., the Party serving the subpoena shall provide pre-notice service to the opposing Party of no less than fifteen (15) days. If the opposing Party fails to move to quash within the fifteen (15) day period, the serving Party may serve the subpoena upon the witness. For purposes of this Paragraph, pre-notice shall be served upon the following persons:

For Plaintiffs:

Randi Kassan at rkassan@thesandersfirm.com; and

Lisa Gorshe at lgorshe@johnsonbecker.com.

For Defendants:

Aaron Rice at aaron.rice@butlersnow.com; and

Bonnie Tuten at bonnie.tuten@butlersnow.com

B. *Document Request Within Subpoena or Deposition Notice:* Witnesses subpoenaed or noticed to testify and to produce documents shall be noticed and served with the subpoena or deposition notice and document request at least thirty (30) days before the scheduled deposition. This provision shall not supersede any preexisting agreement or order governing which documents should be produced and/or when.

C. *Copies*. Extra hard copies of documents which counsel expect to examine the deponent with should be provided to the reporter, primary counsel for the Parties, the deponent, and deponent's counsel during the course of the deposition.

D. *Marking of Deposition Exhibits*. The first time a document is marked as a deposition exhibit, it shall be referred to by the Bates number appearing on the document. Documents that have not been previously produced shall be assigned a Bates number from a range of numbers reserved for this purpose. Thereafter, the exhibit shall be referred to by its deposition exhibit number.

9. **Supplemental Depositions**. The initial noticed deposition shall be presumed to be the complete deposition for discovery purposes barring exceptional circumstances. In the event a party seeks to re-depose a fact witness, the Parties shall meet and confer regarding the request for a second deposition. If the Parties are unable to reach an agreement, the party requesting the deposition may move the Court for an Order permitting the deposition.

SO ORDERED:

Dated: Brooklyn, New York
September 3, 2013

/s/
VIKTOR V. POHORELSKY
United States Magistrate Judge

ButlerSnow 17491658v1

EXHIBIT D

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK	
IN RE PROPECIA (FINASTERIDE) PRODUCT LIABILITY LITIGATION	12-MD-2331 (BMC)(PK)
THIS DOCUMENT APPLIES TO: *Kelly S. Pfaff, individually, on behalf of J.A.P. and C.P., minors, and as Trustee of the Pfaff Family Trust,* *Plaintiffs,* *v.* *Merck & Co., Inc. and Merck Sharp & Dohme Corp.,* *Defendants.*	Case No. 1:15-cv-03355 (BMC) (PK) **NOTICE OF INTENT TO SERVE SUBPOENA**

PLEASE TAKE NOTICE that, pursuant to the applicable Federal Rules of Civil Procedure, Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. ("Merck"), by and through counsel, hereby intend to serve the subpoena attached here to as Exhibit 1.

DATED this the 13th day of August 2020.

Respectfully submitted,

/s/ Charles F. Morrow
Charles F. Morrow
BUTLER SNOW LLP
Crescent Center
6075 Poplar Avenue, Suite 500
Memphis, TN 38119
Telephone: (901) 680-7200
Facsimile: (901) 680-7201
Email: chip.morrow@butlersnow.com

Attorney for Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp.

CERTIFICATE OF SERVICE

I hereby certify that on this date I have caused the foregoing to be served via electronic mail on counsel of record.

Molly Booker
Rachel Fitzpatrick
11 West Jefferson, Suite 1000
Phoenix, AZ 85003
Email: mollyb@hbsslaw.com
rachelf@hbsslaw.com

/s/ Charles F. Morrow

EXHIBIT 1

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of New York

Kelly S. Pfaff, et al.
Plaintiff
v.
Merck & Co., Inc., et al.
Defendant

Civil Action No. 1:15-cv-03355(BMC)(PK)

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: Trace3, Inc., 7565 Irvine Center Drive, Suite 200, Irvine, California 92618 c/o CSC - Lawyers Incorporating Service, 2710 Gateway Oaks Drive, Suite 150N, Sacramento, CA 95833

(Name of person to whom this subpoena is directed)

☑ *Production:* **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See Exhibit A

Place:	Date and Time:
Caroline D. Murray, Venable LLP 101 California Street, Suite 3800 San Francisco, CA 94111	09/11/2020 12:00 am

☐ *Inspection of Premises:* **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 08/13/2020

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Merck & Co., Inc. and Merck Sharp & Dohme Corp., who issues or requests this subpoena, are:
Michael A. Guerra, Venable LLP, 1290 Avenue of the Americas, The Twentieth Floor, New York, NY 10104, MAGuerra@venable.com, (212) 218-2100

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 1:15-cv-03355(BMC)(PK)

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named individual as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

EXHIBIT "A"

DEFINITIONS AND INSTRUCTIONS

Unless the context indicates otherwise, the following words and phrases have the meanings given:

1. "You," "your," and "Trace3" mean and refer to Trace3, Inc., Trace3, LLC, and associated subsidiaries, divisions, departments, affiliates, predecessors, successors, or offices, and all present and former officers, directors, employees, trustees, principals, agents, members, executives, and representatives of Trace3.

2. The term "document" is used in its broadest sense permitted by the Federal Rules of Civil Procedure and means any writing of any kind, including the originals and any non-identical copies, regardless of origin or location, including but not limited to books, pamphlets, periodicals, correspondence, memoranda (including those of telephone or other conversations), letters, reports, records, notes, telegraphs, photographs, films, videotapes, audiotapes, magnetic recordings, digital recordings, computer files, computer disks, emails, pins, text messages, webpages, physician's notes or records, autopsy, x-ray, laboratory or other reports generated by medical, diagnostic or other equipment, charts and any data from which information may be obtained, and copies containing marginal notes or variations of any of the foregoing.

3. "Communication" means any act, action, oral speech, written correspondence, contact, expression of words, thoughts, and/or ideas, or transmission or exchange of data or other information to another person, whether orally, person-to-person, in a group, by telephone, letter, personal delivery, telex, facsimile, and/or any other process, electronic or otherwise. Communications in writing shall include, without limitation, printed, typed handwritten, electronic, and other readable documents.

4. The terms "relate," "related," "relates," or "relating" means concerning, referring to, summarizing, reflecting, constituting, containing, embodying, pertaining to, involved with, mentioning, discussing, consisting of, comprising, showing, commenting on, evidencing, describing, or otherwise relating to the subject matter.

5. The words "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of these requests any Documents which might otherwise be construed to be outside their scope.

6. The use of plural shall be deemed to include the singular and the use of the singular shall be deemed to include the plural.

REQUESTED DOCUMENTS

1. True and correct copies of all records, reports, files, documents, communications, memoranda and all other information related to employment of **John D. Pfaff**, whether maintained in hard copy or electronic format, including hiring documents, promotion documents, attendance reports, performance reports, W-2 and W-4 forms, medical reports and/or any and all other records relating to **John D. Pfaff**'s employment and/or personnel file, and all training and/or educational records, including all courses taken, degrees obtained, and attendance records.

2. True and correct copies of all employment records, workers' compensation records, disability records, social security records, and insurance records, whether maintained in hard copy or electronic format, including Medicare/Medicaid and other public assistance claims applications, statements, eligibility material, claims or claim disputes, resolutions and payments, medical records provided as evidence of services provided, and any other documents or things pertaining to services furnished under Title XVII of the Social Security Act or other forms of public assistance (federal, state, local, or other) relating to **John D. Pfaff**.

3. True and correct copies all records, reports, files, documents, communications, memoranda, and all other information relating to **John D. Pfaff**'s retirement benefits, bonus packages, stocks (including plans and options), trusts, loans, and all other financial information relating to **John D. Pfaff**, whether maintained in hard copy or electronic format.

4. True and correct copies of all records, reports, files, documents, communications, memoranda, media files (including photos, videos, and other media forms), and all other information related to **John D. Pfaff**'s speaking engagements and published works, whether maintained in hard copy or electronic format.

5. True and correct copies of all contracts, invoices, records, reports, files, documents, communications, memoranda, and all other information in your possession, custody, or control relating to any counseling or coaching services in which **John D. Pfaff** was involved, whether maintained in hard copy or electronic format.

6. True and correct copies of all schedules and calendars kept or maintained, whether maintained in hard copy or electronic format, by **John D. Pfaff** or any person who kept or maintained such records on his behalf.

7. True and correct copies of all contracts, invoices, records, reports, files, documents, communications, memoranda, and all other information in your possession, custody, or control relating to **John D. Pfaff**'s resignation, or otherwise-titled departure, including any request for or consideration of reinstatement, from Trace3 whether maintained in hard copy or electronic format.

8. True and correct copies of all records, files, documents, communications, memoranda, and all other information in your possession, custody, or control for the time period January 1, 2012 to the present discussing or reflecting in any manner the role, duties, position, standing, opinions, state of mind and/or relationships of **John D. Pfaff** to which he was an author

or recipient. This request includes, but is not limited to, items contained in email accounts, document management systems, shared drives, computer hardware, hard copy files or any other source of data maintained by Trace3. Furthermore, this request does not seek any information that would be subject to the attorney-client privilege nor any information that would reveal a trade secret of Trace3.

9. True and correct copies of Trace3's agreements, records, policies, or documents concerning employees' electronic devices, both company-provided and employee-provided, for the period of January 1, 2004, through January 1, 2014, whether maintained in hard copy or electronic format.

10. True and correct copies of Trace3's agreements, records, policies, or documents, for the period of January 1, 2013, through the present, concerning preservation and destruction of electronically stored information on employees' company-provided and employee-provided electronic devices both during employment and following employees' departure from Trace3, whether maintained in hard copy or electronic format.

11. True and correct copies of Trace3's agreements, records, policies, or documents, for the period of January 1, 2013, through the present, concerning the use of employees' e-mail accounts, including the accessibility thereof following employees' departure from Trace3, whether maintained in hard copy or electronic format.

12. True and correct copies of agreements, records, policies, documents, or communications reflecting **John D. Pfaff**'s usernames or passwords, including, but not limited to, those associated with his Trace3 e-mail account, cloud accounts, and company-provided or employee-provided electronic devices, whether maintained in hard copy or electronic format.

13. All electronically stored files or parts of files containing any of the information requested in any of the preceding items which have been "deleted" but which may nevertheless be recoverable by any means.

The above list of types of records and other information to be disclosed is intended to be illustrative and not exhaustive. This listing is not meant to be exclusive.

54300378.v1

AUTHORIZATION AND CONSENT
TO RELEASE RECORDS AND PROTECTED HEALTH INFORMATION
(Excluding psychotherapy notes)

Patient Name: John D. Pfaff
Social Security Number: XXX-XX-6242
Date of Birth: September 27, 1972

Provider Name: Trace3, 7565 Irvine Center Drive, Suite 200, Irvine, CA 92618

TO: All physicians, hospitals, clinics and institutions, pharmacists and other healthcare providers

The Veteran's Administration and all Veteran's Administration hospitals, clinics, physicians and employees

The Social Security Administration

The Internal Revenue Service

Open Records, Administrative Specialist, Department of Workers' Claims

All employers or other persons, firms, corporations, schools and other educational institutions

The undersigned individual hereby authorizes each entity included in any of the above categories to disclose and furnish to **Litigation Management, Inc, 6600 Parkland Blvd, Mayfield Hts., OH 44124 as an agent for Butler, Snow, O'Mara, Stevens & Cannada, PLLC, 1020 Highland Colony Parkway, Suite 1400, Ridgeland, MS 39157,** and its authorized representatives, true and correct copies of all records, reports, files, documents, correspondence, memoranda and all other information related to the physical and mental health of the undersigned individual, regardless of the form of such information, including, without limitation, all notes of physicians, nurses, psychologists, counselors, dentists and other persons who have provided or who are providing health care to the undersigned individual, all radiology, pathology (including HIV test results, genetic testing information, and alcohol and drug abuse treatment) and other diagnostic test and laboratory results, records and reports, all prescription records, all surgical procedure records and reports, all dental records, all histories and summaries, all forms and other information related to admission of the undersigned to or discharge of the undersigned from a clinic, hospital or other health care facility, all surgical procedure and other consent forms, all bills, invoices, claim forms, records and other payment information, including payment by Medicaid/Medicare and other public assistance programs, insurance companies and by other persons. Notwithstanding the broad scope of the above disclosure request, the undersigned does not authorize the disclosure of "psychotherapy notes" as such term is defined by the Health Insurance Portability and Accountability Act, 45 CFR §164.501.

The undersigned also authorizes the disclosure of all records, reports, files, documents, correspondence, memoranda and all other information related to employment of the undersigned,

including attendance reports, performance reports, W-2 and W-4 forms, medical reports and/or any and all other records relating to my past and present employment, and all educational records, including all courses taken, degrees obtained, and attendance records.

This authorization includes to the extent such records currently exist and are in the Provider's possession, employment records, workers' compensation records, disability records, social security records, and insurance records, including Medicare/Medicaid and other public assistance claims applications, statements, eligibility material, claims or claim disputes, resolutions and payments, medical records provided as evidence of services provided, and any other documents or things pertaining to services furnished under Title XVII of the Social Security Act or other forms of public assistance (federal, state, local, or other). This listing is not meant to be exclusive.

The above list of types of records and other information to be disclosed is intended to be illustrative and not exhaustive. This authorization does not authorize ex parte communication concerning same.

- This authorization provides for the disclosure of the above-named patient's protected health information for purposes of the following litigation matter: Pfaff, et al. *v. Merck & Co., Inc., et al.*, Case No.: 1:15cv03355BMC-PK .

- The undersigned individual is hereby notified and acknowledges that any health care provider or health plan disclosing the above requested information may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs this authorization.

- The undersigned individual is hereby notified and acknowledges that he or she may revoke this authorization by providing written notice either to **Litigation Management, Inc, 6600 Parkland Blvd, Mayfield Hts., OH 44124 or Butler, Snow, O'Mara, Stevens & Cannada, PLLC, Attention: Alyson B. Jones, 1020 Highland Colony Parkway, Suite 1400, Ridgeland, MS 39157** and/or to one or more entities listed in the above categories, except to the extent that any such entity has taken action in reliance on this authorization.

- The undersigned is hereby notified and acknowledges he or she is aware of the potential that protected health information disclosed and furnished to the recipient pursuant to this authorization is subject to redisclosure by the recipient for the purposes of this litigation in a manner that will not be protected by the Standards for the Privacy of Individually Identifiable Health Information contained in the HIPAA regulations (45 CFR §§164.500-164.534).

- The undersigned is hereby notified that he/she is aware that any and all protected health information disclosed and furnished to **Litigation Management, Inc, as an agent for Butler, Snow, O'Mara, Stevens & Cannada, PLLC** pursuant to this authorization will be shared with any and all co-defendants in the matter of Pfaff, et al. *v. Merck & Co., Inc., et al.*, Case No.: 1:15cv03355-BMC-PK and is subject to redisclosure by the recipient for the purposes of this litigation in a manner that will not be protected by the Standards for the Privacy of Individually Identifiable Health Information contained in the HIPAA regulations (45 CFR §§164.500-164.534).

- I understand that information disclosed under this authorization could relate to, and I hereby authorize the disclosure of, information regarding treatment and testing for drug or alcohol abuse, Acquired Immunodeficiency Syndrome (AIDS), Human Immunodeficiency Virus (HIV), sexually transmitted diseases, Sickle Cell Anemia, Tuberculosis and Genetic testing and counseling.

- A photocopy of this authorization shall be considered as effective and valid as the original, and this authorization will remain in effect until the later of: (i) the date of settlement or final disposition of Pfaff, et al. *v. Merck & Co., Inc., et al.*, Case No.: 1:15cv03355-BMC-PK or (ii) five (5) years after the date of signature of the undersigned below

I have carefully read and understand the above and do hereby expressly and voluntarily authorize the disclosure of all of my above information to Litigation Management, Inc, 6600 Parkland Blvd, Mayfield Hts., OH 44124 as an agent for Butler, Snow, O'Mara, Stevens & Cannada, PLLC, 1020 Highland Colony Parkway, Suite 1400, Ridgeland, MS 39157, and its authorized representatives, by any entities included in the categories listed above.

Date: 10/26/19

Signature of Individual or Individual's Representative

Individual's Name and Address:

Kelly Pfaff

Printed Name of Individual's Representative (If applicable)

Widowed Spouse

Relationship of Representative to Individual (If applicable)

Description of Representative's authority to act for Individual (If applicable)

This authorization is designed to be in compliance with the Health Insurance Portability and Accountability Act, and the regulations promulgated thereunder, 45 CFR Parts 160 and 164 (collectively, "HIPAA").

ButlerSnow 14979437v1